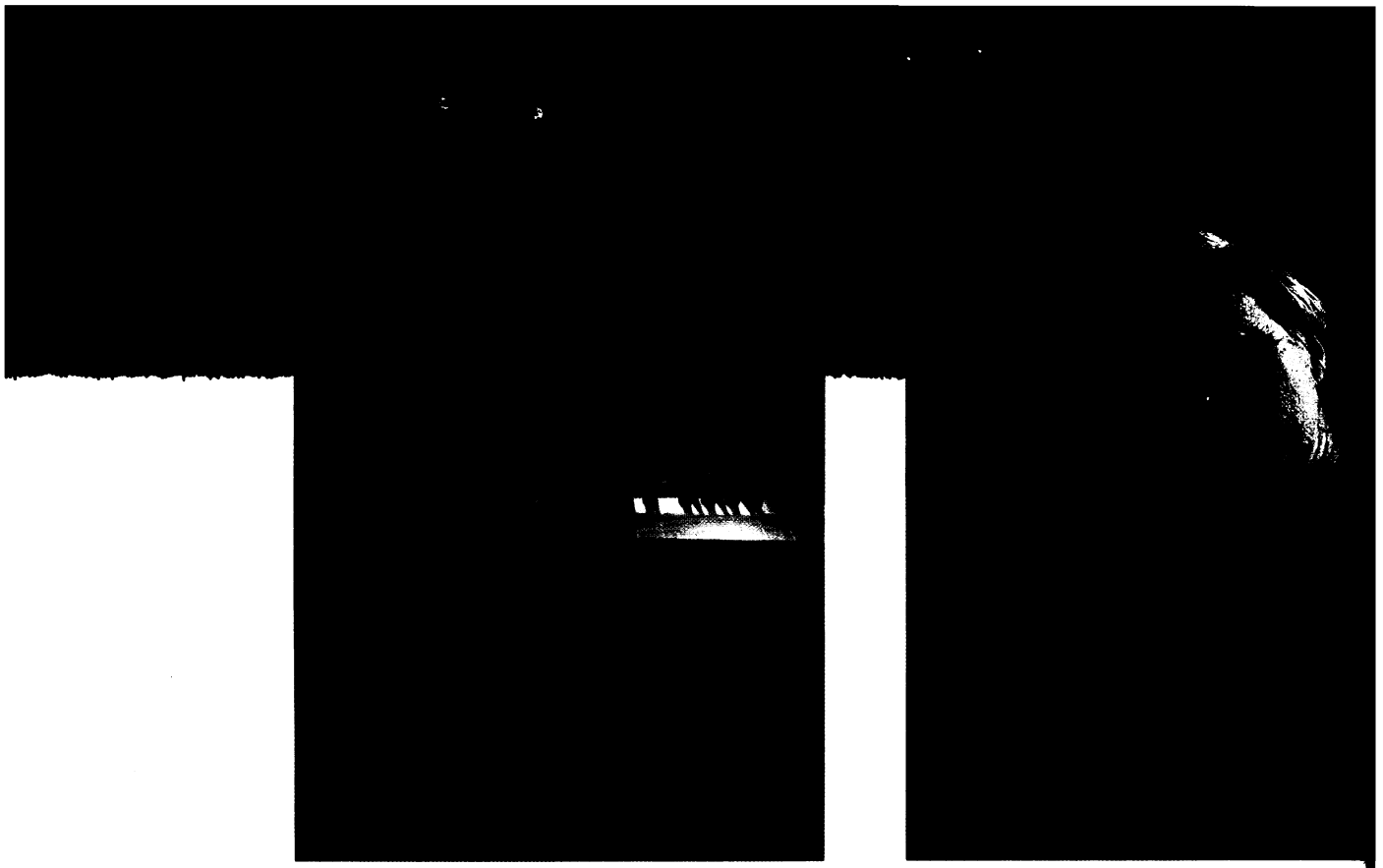

Only Dalmane® *(flurazepam HCl/Roche)* consistently achieves these important goals of hypnotic therap

1. Prompt sleep onset

Difficulty falling asleep is often the primary complaint of insomnia patients.[1,2] And when a hypnotic fails to reduce sleep induction time at the prescribed dosage level, some patients may be more susceptible to multiple dosing on their own.[3] So prompt sleep onset can be an essential consideration in the choice of hypnotic therapy.

Objective sleep laboratory studies show that for the first three nights, Dalmane is unsurpassed in achieving this important goal of hypnotic therapy. *And after 14 nights, Dalmane is more effective than any other hypnotic tested in inducing prompt sleep onset.* All other hypnotics tested declined in efficacy after two weeks of therapy, and *temazepam was shown to have no significant effect on sleep onset.*[4,5]

2. Less time awake after sleep onset

In sleep laboratory studies, Dalmane redu wake time after sleep onset by 61% ($p < 0.0$ on the first three nights of therapy. Temazepa pentobarbital failed to maintain efficacy in th eter through two weeks of therapy; however, Dalmane continued to be effective through 2 consecutive nights.[6]

3. Less total time awa

Helping patients sleep longer and with few awakenings is another therapeutic goal where Dalmane stands apart. Dalmane decreased to wake time by 51% ($p < 0.01$) on the first th nights of therapy in sleep laboratory studies— level of significant improvement unsurpassed b any other hypnotic tested.[4]

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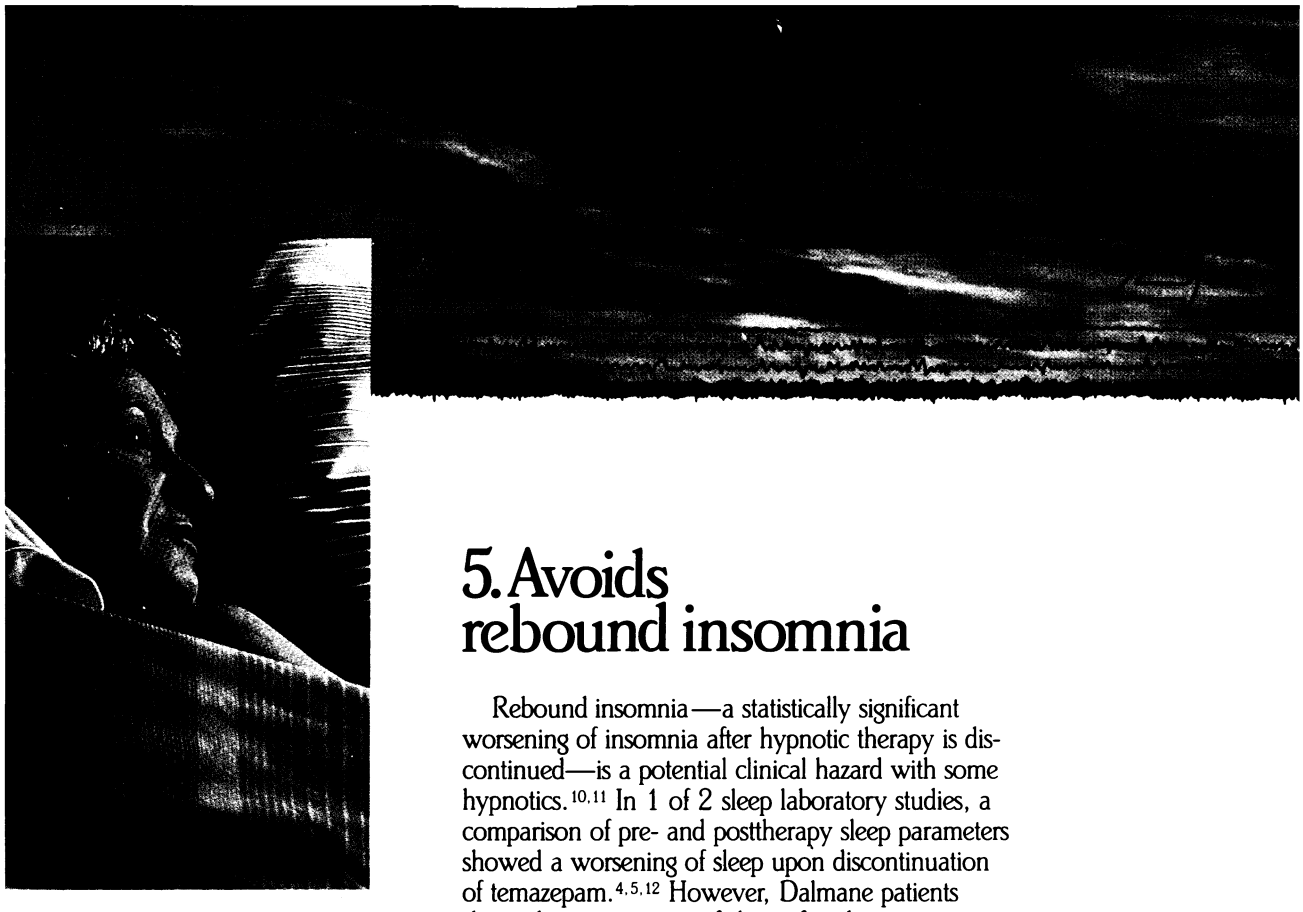

npared with placebo baselines in
ory, Dalmane (flurazepam HCl/
l a 35% ($p < 0.01$) decline in
nings.[7] Together these results point
Dalmane in helping the insomniac
more restful night's sleep.

incidence of
g hangover

ry findings on the quality of
l sleep are complemented by clini-
quality of awakening after a night
one study comparing Dalmane with
majority of patients ($p < 0.001$)
ept better" and awoke feeling
rt after taking Dalmane.[8]
pective study of 2542 hospitalized
showed only a 3.1% incidence of
ss—"morning hangover"—with
residual effects are usually dose-
hould be cautioned about drinking
or operating hazardous machinery
ince the risk of oversedation,
ataxia increases with larger doses
15-mg dosage is generally
is contraindicated in pregnancy.

5. Avoids rebound insomnia

Rebound insomnia—a statistically significant worsening of insomnia after hypnotic therapy is discontinued—is a potential clinical hazard with some hypnotics.[10,11] In 1 of 2 sleep laboratory studies, a comparison of pre- and posttherapy sleep parameters showed a worsening of sleep upon discontinuation of temazepam.[4,5,12] However, Dalmane patients showed no worsening of sleep after discontinuation,[4] a benefit that can help you achieve your ultimate therapeutic goal—untroubled and unaided sleep.

References: **1.** Karacan I *et al: Soc Sci Med 10*:239-243, May 1976. **2.** Bixler EO *et al: Am J Psychiatry 136*:1257-1262, Oct 1979. **3.** National Institute on Drug Abuse, U.S. Dept. Health, Education, and Welfare: *Sedative-Hypnotic Drugs: Risks and Benefits*, edited by Cooper JR; Rockville, MD, 1977. **4.** Kales A *et al: J Clin Pharmacol 17*:207-213, Apr 1977, and Data on file, Hoffmann-La Roche Inc., Nutley, NJ. **5.** Bixler EO *et al: J Clin Pharmacol 18*:110-118, Feb-Mar 1978. **6.** Data on file, Hoffmann-La Roche Inc., Nutley, NJ. **7.** Kales A *et al: Clin Pharmacol Ther 19*:576-583, May 1976. **8.** Zimmerman AM: *Curr Ther Res 13*:18-22, Jan 1971. **9.** Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther 21*:355-361, Mar 1977. **10.** Kales A *et al: JAMA 241*:1692-1695, Apr 20, 1979. **11.** Kales A, Scharf MB, Kales JD: *Science 201*:1039-1041, Sep 15, 1978. **12.** Mitler MM *et al: Br J Clin Pharmacol 8* (1):63S-68S, 1979.

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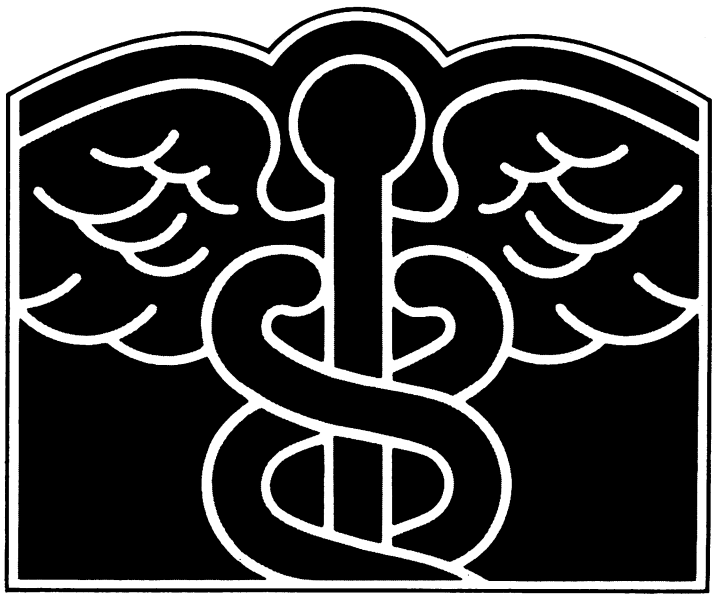

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Epidemic Kaposi's Sarcoma & Opportunistic Infections in Homosexual Men:

Expression Of An Acquired Immunoregulatory Disorder

Thursday-Saturday
March 17-19, 1983

Organizing Committee:
Alvin E. Friedman-Kien, M.D.
Linda Laubenstein, M.D.
Franco Muggia, M.D.

This symposium is designed to offer a broad overview of the recently recognized epidemic of Kaposi's sarcoma and acquired immunoregulatory disorders in homosexual men. The program affords an unusual opportunity to analyze the interrelationships between the environmental, genetic and immunologic factors in the pathogenesis of this unique neoplasm and its multifaceted clinical and basic science implications

PROGRAM TOPICS

- Clinical expression and treatment modalities for the epidemic form of Kaposi's sarcoma: similarities and differences from the classical presentation of the disease.
- Details of the acquired immunoregulatory disorder including clinical and **in vitro** characterization of the defects in cell mediated immunity, possible role of circulating immune complexes and HLA alloantigens.
- Epidemiologic investigations aimed at defining the causes of this outbreak in homosexual men; the possible roles of changing lifestyles, use of "recreational" drugs and sexually transmitted diseases.
- The spectrum of opportunistic infections, such as **Pneumocystis carinii** pneumonia, cytomegalovirus, Epstein-Barr virus, cryptococcosis and atypical Mycobacterium: The potential role of viruses as the causative agent of the immunologic disorder.
- A workshop on Saturday morning will focus on the practical clinical management of common diagnostic and therapeutic problems encountered in patients with the acquired immunodeficiency syndrome, such as lymphadenopathy, diarrhea, unexplained fever and pulmonary infiltrates.

A NATIONALLY DISTINGUISHED GUEST FACULTY WILL PARTICIPATE

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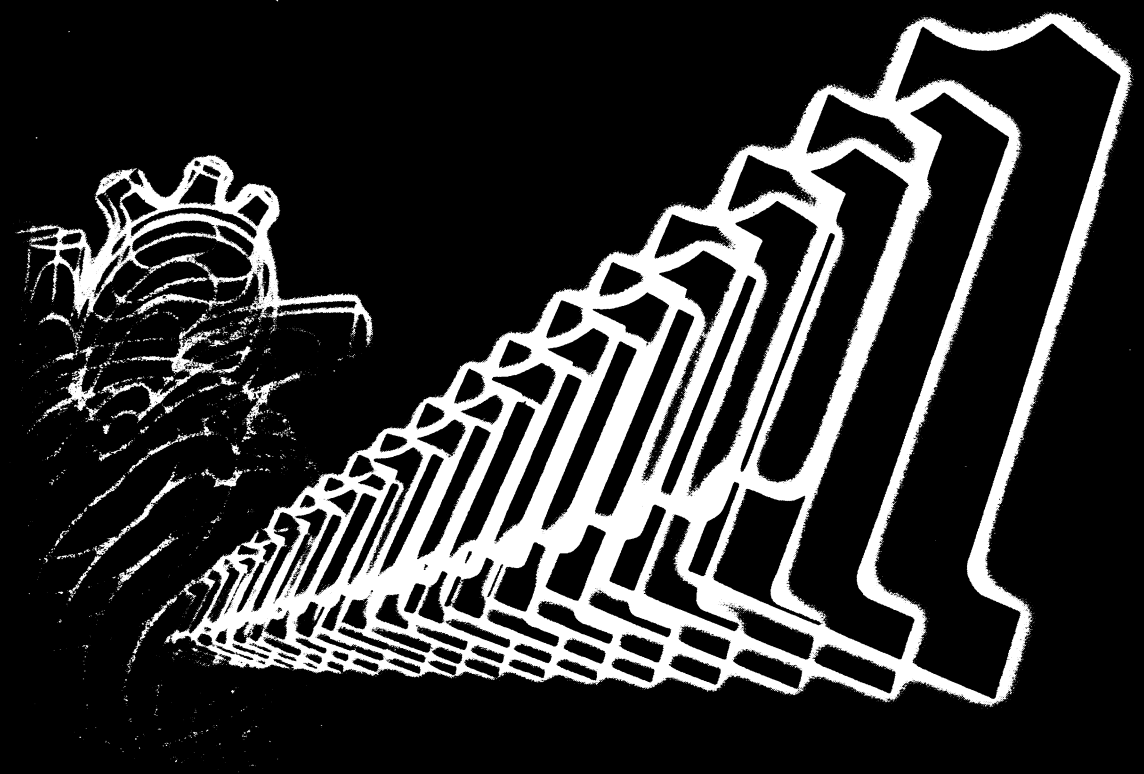

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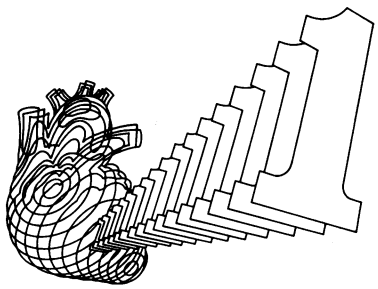

CORGARD®
nadolol tablets
40 mg, 80 mg, 120 mg, 160 mg scored tablets

CORGARD® TABLETS
Nadolol Tablets

DESCRIPTION: Corgard (nadolol) is a synthetic nonselective beta-adrenergic receptor blocking agent.

CONTRAINDICATIONS: Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS).

WARNINGS: Cardiac Failure—Sympathetic stimulation may be a vital component supporting circulatory function in congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well-compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure; therefore, at first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of $beta_2$ receptors.

Major Surgery — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents.

Diabetes and Hypoglycemia — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs.

Thyrotoxicosis — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

PRECAUTIONS: Impaired Hepatic or Renal Function — Use nadolol with caution in presence of either of these conditions (see DOSAGE AND ADMINISTRATION section of package insert).

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at first sign or symptom of impending failure.

Drug Interactions — Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. When treating patients with nadolol plus a catecholamine-depleting agent, carefully observe for evidence of hypotension and/or excessive bradycardia which may produce vertigo, syncope, or postural hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility — In 1 to 2 years' oral toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lesions.

Pregnancy — In animal reproduction studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits (but not in rats or hamsters) at doses 5 to 10 times greater (on a mg/kg basis) than maximum indicated human dose; no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women; therefore, use nadolol in pregnant women only if potential benefit justifies potential risk to the fetus.

Nursing Mothers — It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when nadolol is administered to a nursing woman. Animal studies showed that nadolol is found in the milk of lactating rats.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Most adverse effects have been mild and transient and have rarely required nadolol withdrawal.

Cardiovascular — Bradycardia with heart rates of less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approximately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta-blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Nervous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol.

Potential Adverse Effects: Although other adverse effects reported with other beta-adrenergic blocking agents have not been reported with nadolol, they should be considered potential adverse effects of nadolol. **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place; short-term memory loss, emotional lability with slightly clouded sensorium; decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm; respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash.

OVERDOSAGE: Nadolol can be removed from the general circulation by hemodialysis. In addition to gastric lavage, employ the following measures as appropriate. In determining duration of corrective therapy, take note of long duration of effect of nadolol.

Excessive Bradycardia — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Cardiac Failure — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation.

Hypotension — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.)

Bronchospasm — Administer a $beta_2$-stimulating agent and/or a theophylline derivative.

DOSAGE: For all patients, DOSAGE MUST BE INDIVIDUALIZED.

For **angina pectoris,** usual initial dose is 40 mg q.d.; gradually increase in 40 to 80 mg increments at 3 to 7 day intervals until optimum clinical response or pronounced slowing of the heart rate; usual maintenance dose is 80 to 240 mg q.d. (most patients respond to 160 mg or less daily). If treatment is to be discontinued, reduce dosage gradually over a period of 1 to 2 weeks (see WARNINGS).

For **hypertension,** usual initial dose is 40 mg q.d.; gradually increase in 40 to 80 mg increments until optimum blood pressure reduction is achieved; usual maintenance dose is 80 to 320 mg q.d. (rarely, doses up to 640 mg may be needed).

Patients with renal failure require adjustment in dosing interval — see package insert for dosage in these patients.

For full prescribing information, consult package insert.

HOW SUPPLIED: In scored tablets containing 40, 80, 120, or 160 mg nadolol per tablet in bottles of 100 and 1000 tablets and in Unimatic® unit-dose packs of 100 tablets. The 40 mg and 80 mg tablets are also available in convenience packages containing 4 blister cards of 7 tablets each.

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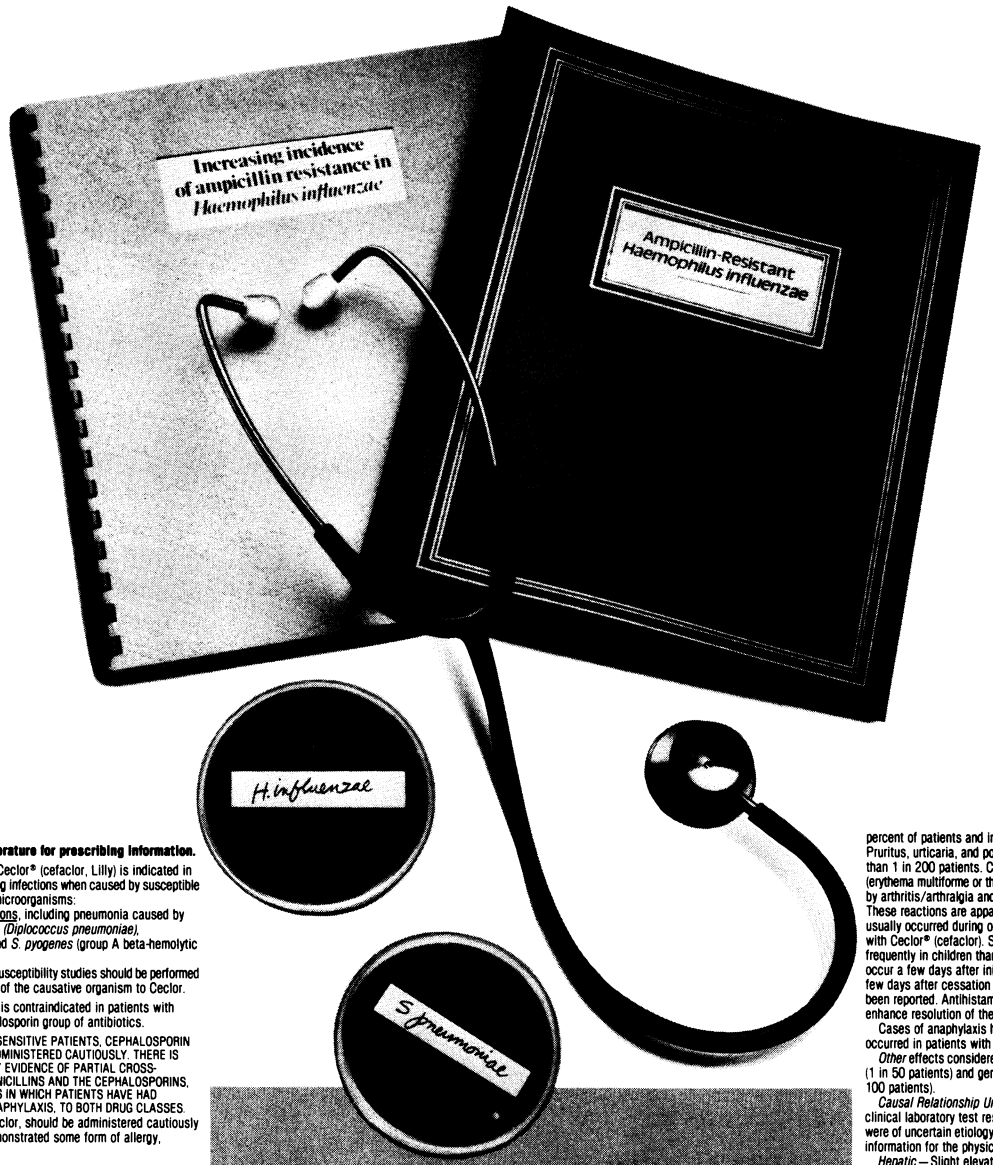
 Issued: January 1982 512-501

An added complication... in the treatment of bacterial bronchitis*



Some ampicillin-resistant strains of Haemophilus influenzae—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Ceclor.®

In clinical trials, patients with bacterial bronchitis due to susceptible strains of Streptococcus pneumoniae, H. influenzae, S. pyogenes (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Ceclor.[1]

Ceclor®
cefaclor
Pulvules®, 250 and 500 mg

Brief Summary.
Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae,* and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Precautions: If an allergic reaction to cefaclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of cefaclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coomb testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such a condition, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Usage in Pregnancy—Although no teratogenic or antifertility effects were seen in reproduction studies in mice and rats receiving up to 12 times the maximum human dose or in ferrets given three times the maximum human dose, the safety of this drug for use in human pregnancy has not been established. The benefits of the drug in pregnant women should be weighed against a possible risk to the fetus.

Usage in Infancy—Safety of this product for use in infants less than one month of age has not been established.

Adverse Reactions: Adverse effects considered related to cefaclor therapy are uncommon and are listed below:

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70) and nausea and vomiting (1 in 90).

As with other broad-spectrum antibiotics, colitis, including rare instances of pseudomembranous colitis, has been reported in conjunction with therapy with Ceclor.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor® (cefaclor). Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200). [100281R]

*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.[8]

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285.

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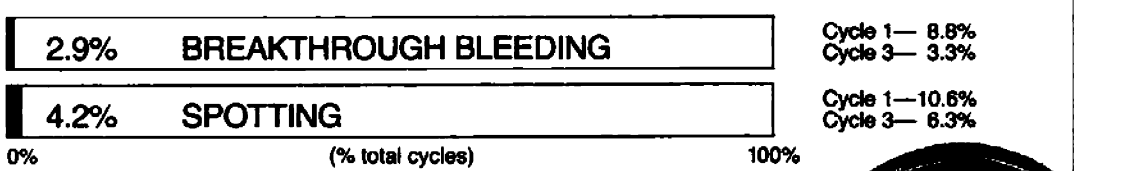
The dosage is lower than "low." Lo/Ovral® contains an "extra-low" total hormone dose—30 mcg ethinyl estradiol and just 0.3 mg norgestrel. Even at this extra-low dose there was no reduction in contraceptive effectiveness. Nor any overall increase in breakthrough bleeding.*

BENEFIT #2: EARLY CYCLE BREAKTHROUGH PROTECTION

Lo/Ovral® offers your patients protection against breakthrough bleeding and spotting when they need it most—in the early cycles.* That's when they're usually most vulnerable to intermenstrual bleeding.

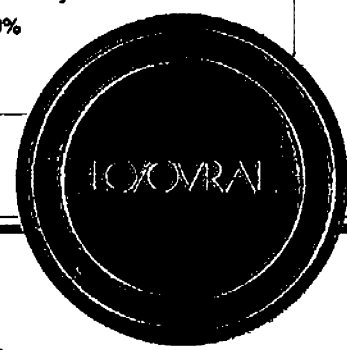
And in clinical trials totalling 22,489 cycles Lo/Ovral achieved a near-spotless record.* Just look below.



*Serious as well as minor adverse reactions have been reported following the use of all oral contraceptives.

See full prescribing information.

IMPORTANT INFORMATION ON FOLLOWING PAGE.



EXTRA-LOW DOSE LO/OVRAL® 30 mcg

each tablet contains 0.3 mg norgestrel with 0.03 mg ethinyl estradiol, Wyeth.

Oral contraceptive with a near-spotless record.

Laboratories
Philadelphia, PA 19101

IN BRIEF:
Indications and Usage—LO/OVRAL® is indicated for the prevention of pregnancy in women who elect to use oral contraceptives (OC's) as a method of contraception.
Contraindications—OC's should not be used in women with any of the following conditions. 1. Thrombophlebitis or thromboembolic disorders. 2. A past history of deep-vein thrombophlebitis or thromboembolic disorders. 3. Cerebral-vascular or coronary-artery disease. 4. Known or suspected carcinoma of the breast. 5. Known or suspected estrogen-dependent neoplasia. 6. Undiagnosed abnormal genital bleeding. 7. Known or suspected pregnancy (see Warning No. 5). 8. Benign or malignant liver tumor which developed during use of OC's or other estrogen-containing products.
Warnings

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

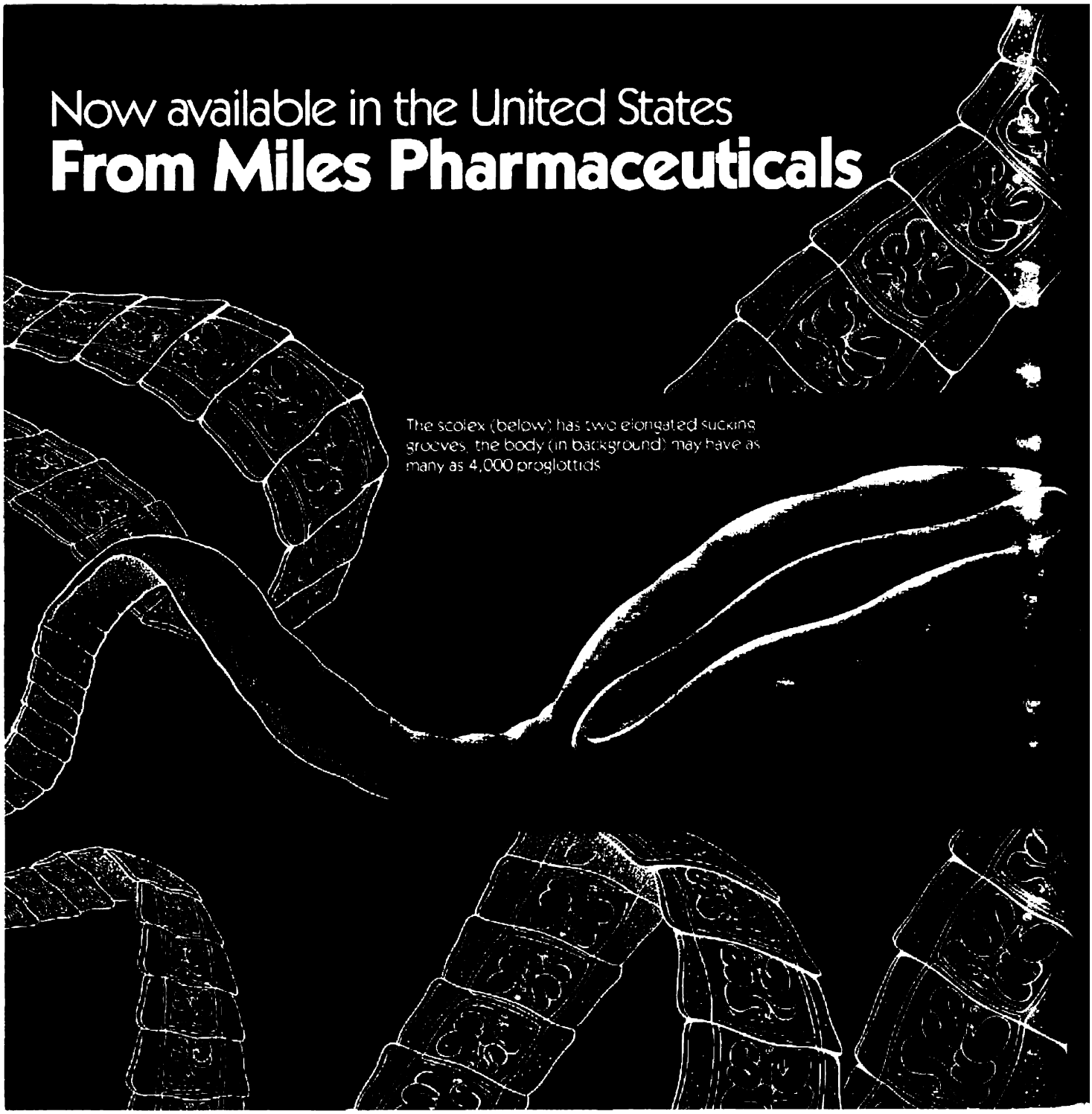
The use of oral contraceptives is associated with increased risk of several serious conditions, including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems*—An increased risk of thromboembolic and thrombotic disease associated with use of OC's is well established. Three principal studies in Great Britain and 3 in the U.S. have demonstrated increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic. These studies estimate that users of OC's are 4 to 11 times more likely than nonusers to develop these diseases without evident cause.
CEREBROVASCULAR DISORDERS—In a collaborative American study of cerebrovascular disorders in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers and the risk of thrombotic stroke was 4 to 9.5 times greater in users than in nonusers.
MYOCARDIAL INFARCTION (MI)—An increased risk of MI associated with use of OC's has been reported, confirming a previously suspected association. These studies, conducted in the UK, found, as expected, that the greater the number of underlying risk factors for coronary artery disease (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of pre-eclamptic toxemia) the higher the risk of developing MI, regardless of whether the patient was an OC user or not. OC's, however, were found to be a clear additional risk factor. In terms of relative risk, it has been estimated that OC users who do not smoke (smoking is considered a major predisposing condition to MI) are about twice as likely to have a fatal MI as nonusers who do not smoke. OC users who are also smokers have about a 5-fold increased risk of fatal MI compared to users who do not smoke, but about a 10- to 12-fold increased risk compared to nonusers who do not smoke. Furthermore, amount of smoking is also an important factor. In determining importance of these relative risks, however, baseline rates for various age groups must be given serious consideration. Importance of other predisposing conditions mentioned above in determining relative and absolute risks has not as yet been quantified; quite likely the same synergistic action exists, but perhaps to a lesser extent.
RISK OF DOSE—In an analysis of data derived from several national adverse-reaction reporting systems, British investigators concluded that risk of thromboembolism, including coronary thrombosis, is directly related to dose of estrogen in OC's. Preparations containing 100 mcg or more of estrogen were associated with higher risk of thromboembolism than those containing 50-80 mcg. Their analysis did suggest, however, that quantity of estrogen may not be the sole factor involved. This finding has been confirmed in the U.S.
ESTIMATE OF EXCESS MORTALITY FROM CIRCULATORY DISEASES—A large prospective study carried out in the UK estimated the mortality rate per 100,000 women per year from diseases of the circulatory system for users and nonusers of OC's according to age, smoking habits, and duration of use. Overall excess death rate annually from circulatory diseases for OC users was estimated to be 20 per 100,000 (ages 15-34—5/100,000; ages 35-44—33/100,000; ages 45-49—140/100,000), risk being concentrated in older women, in those with long duration of use, and in cigarette smokers. It was not possible, however, to examine interrelationships of age, smoking, and duration of use, nor to compare effects of continuous vs. intermittent use. Although the study showed a 10-fold increase in death due to circulatory diseases in users for 5 or more years, all these deaths occurred in women 35 or older. Until larger numbers of women under 35 with continuous use for 5 or more years are available, it is not possible to assess magnitude of relative risk for this younger group. Available data from a variety of sources have been analyzed to estimate risk of death associated with various methods of contraception. Estimates of risk of death for each method include combined risk of contraceptive method (e.g., thromboembolic and thrombotic disease in the case of OC's) plus risk attributable to pregnancy or abortion in event of method failure. This latter risk varies with effectiveness of method. The study concluded that mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of OC's in women over 40 who smoke. Lowest mortality is associated with condom or diaphragm backed up by early abortion. Risk of thromboembolic and thrombotic disease associated with OC's increases with age after about 30 and, for MI, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of pre-eclamptic toxemia, and especially cigarette smoking. Physician and patient should be alert to earliest manifestations of thromboembolic and thrombotic disorders (e.g., thrombophlebitis, pulmonary embolism, cerebrovascular insufficiency, coronary occlusion, retinal thrombosis, and mesenteric thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.
A 4- to 6-fold increased risk of postsurgery thromboembolic complications has been reported in OC users.
If feasible, OC's should be discontinued at least 4 weeks before surgery of a type associated with increased risk of thromboembolism or prolonged immobilization.
2. *Ocular Lesions*—There have been reports of neuro-ocular lesions such as optic neuritis or retinal thrombosis associated with use of OC's. Discontinue OC's if there is unexplained, sudden or gradual, partial or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal-vascular lesions, and institute appropriate diagnostic and therapeutic measures.
3. *Carcinoma*—Long-term continuous administration of either natural or synthetic estrogen in certain animal species increases frequency of carcinoma of the breast, cervix, vagina, and liver. Certain synthetic progestogens, none currently contained in OC's, have been noted to increase incidence of mammary nodules, benign and malignant, in dogs. In humans, 3 case-control studies have reported an increased risk of endometrial carcinoma associated with prolonged use of exogenous estrogen in postmenopausal women. One publication reported on the first 21 cases submitted by physicians to a registry of cases of adenocarcinoma of the endometrium in women under 40 on OC's. Of cases found in women without predisposing risk factors (e.g., irregular bleeding at the time OC's were first given, polycystic ovaries), nearly all occurred in women who had used a sequential OC. These are no longer marketed. No evidence has been reported suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only OC's. Several studies have found no increase in breast cancer in women taking OC's or estrogens. One study, however, while also noting no overall increased risk of breast cancer in women on OC's, found an excess risk in subgroups of OC users with documented benign breast disease. Reduced occurrence of benign breast tumors in users of OC's has been well documented. In summary, there is at present no confirmed evidence from human studies of increased risk of cancer associated with OC's. Close clinical surveillance of all women on OC's is, nevertheless, essential. In all cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer or with breast nodules, fibrocystic disease, or abnormal mammograms should be monitored with particular care if they elect to use OC's.
4. *Hepatic Tumors*—Benign hepatic adenomas have been found to be associated with use of OC's. One study showed that OC's with high hormonal potency were associated with higher risk than lower potency OC's. Although benign, hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage. This has been reported in short-term as well as long-term users. Two studies relate risk with duration of use of OC's, the risk being much greater after 4 or more years' use. While hepatic adenoma is rare, it should be considered in women presenting abdominal pain and tenderness, abdominal mass or shock. A few cases of hepatocellular carcinoma have been reported in women on OC's. Relationship of these drugs to this type of malignancy is not known.
5. *Use in or Immediately Preceding Pregnancy, Birth Defects in Offspring, and Malignancy in Female Offspring*—Use of female sex hormones—both estrogenic and progestational agents—during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a nonsteroidal estrogen, have increased risk of developing in later life a form of vaginal or cervical cancer ordinarily extremely rare. This risk has been estimated to be of the order of 1 in 1,000 exposures or less. Although there is no evidence now that OC's further enhance risk of developing this type of malignancy, such patients should be monitored with particular care if they elect to use OC's. Furthermore, 30 to 90% of such exposed women have been found to have epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether this condition is a precursor of vaginal malignancy. Male children so exposed may develop abnormalities of the urogenital tract. Although similar data are not available with use of other estrogens, it cannot be presumed they would not induce similar changes. An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with use of sex hormones, including OC's, in pregnancy. One case-control study estimated a 4.7-fold increase in risk of limb-reduction defects in infants exposed in utero to sex hormones (OC's, hormonal withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some exposures involved only a few days. Data suggest that risk of limb-reduction defects in exposed fetuses is somewhat less than 1 in 1,000 live births. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well-controlled studies that progestogens are effective. There is some evidence that triploidy and possibly other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing OC's. Embryos with these anomalies are virtually always aborted spontaneously. Whether there is an overall increase in spontaneous abortion of pregnancies conceived soon after stopping OC's is unknown. It is recommended that, for any patient who has missed 2 consecutive periods, pregnancy should be ruled out before continuing OC's. If the patient has not adhered to the prescribed schedule, the possibility of pregnancy should be considered at time of first missed period, and further use of OC's should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus, and advisability of continuation of the pregnancy should be discussed. It is also recommended that women who discontinue OC's with intent of becoming pregnant use an alternate form of contraception for a period of time before attempting to conceive. Many clinicians recommend 3 months, although no precise information is available on which to base this. The administration of progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.
6. *Gallbladder Disease*—Studies report increased risk of surgically confirmed gallbladder disease in users of OC's and estrogens. In one study, increased risk appeared after 2 years' use and doubled after 4 or 5 years' use. In one of the other studies, increased risk was apparent between 6 and 12 months' use.
7. *Carbohydrate and Lipid Metabolic Effects*—Decrease in glucose tolerance has been observed in a significant percentage of patients on OC's. For this reason, prediabetic and diabetic patients should be carefully observed while on OC's. Increase in triglycerides and total phospholipids has been observed in patients on OC's; clinical significance of this finding remains to be defined.
8. *Elevated Blood Pressure*—Increase in blood pressure has been reported in patients on OC's. In some women, hypertension may occur within a few months of beginning OC's. In the 1st year of use, prevalence of women with hypertension is low in users and may be no higher than that of a comparable group of nonusers. Prevalence in users increases, however, with longer exposure, and in the 5th year of use is 2½ to 3 times the reported prevalence in the 1st year. Age is also strongly correlated with development of hypertension in OC users. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure on OC's. Hypertension that develops as a result of taking OC's usually returns to normal after discontinuing the drug.
9. *Headache*—Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of OC's and evaluation of the cause.
10. *Bleeding Irregularities*—Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing OC's. In breakthrough bleeding, as in all cases of irregular vaginal bleeding, nonfunctional causes should be borne in mind. In undiagnosed persistent or recurrent abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy. If pathology has been excluded, time or change to another OC may solve the problem. Changing to an OC with a higher estrogen content, while potentially useful in minimizing menstrual irregularity, should be done only if necessary, since this may increase risk of thromboembolic disease. Women with past history of oligomenorrhea or secondary amenorrhea or young women without regular cycles may have a tendency to remain anovulatory or to become amenorrheic after discontinuing OC's. Women with these pre-existing problems should be advised of this possibility and encouraged to use other methods. Post-use anovulation, possibly prolonged, may also occur in women without previous irregularities.
11. *Ectopic Pregnancy*—Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.
12. *Breast-feeding*—OC's given in the postpartum period may interfere with lactation and decrease quantity and quality of breast milk. Furthermore, a small fraction of the hormones in OC's has been identified in the milk of mothers on OC's; effects, if any, on the breast-fed child have not been determined. If feasible, defer OC's until infant has been weaned.
Precautions—GENERAL—1. A complete medical and family history should be taken prior to initiation of OC's. Pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen and pelvic organs, including Pap smear and relevant laboratory tests. As a general rule OC's should not be prescribed for longer than 1 year without another physical examination.
2. Under influence of estrogen-progestogen preparations, pre-existing uterine leiomyomata may increase in size.
3. Patients with history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree. Patients becoming significantly depressed while on OC's should stop OC's and use an alternate method to try to determine whether the symptom is drug-related.
4. OC's may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention, such as convulsive disorders, migraine syndrome, asthma, or cardiac or renal insufficiency.
5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence while on OC's. If jaundice develops, OC's should be discontinued.
6. Steroid hormones may be poorly metabolized in patients with impaired liver function and should be administered with caution.
7. OC users may have disturbances in normal tryptophan metabolism which may result in a relative pyridoxine deficiency. Clinical significance is undetermined.
8. Serum folate levels may be depressed by OC's. Since the pregnant woman is predisposed to development of folate deficiency and incidence of folate deficiency increases with increasing gestation, it is possible that if a woman becomes pregnant shortly after stopping OC's, she may have a greater chance of developing folate deficiency and complications attributed to this deficiency.
9. The pathologist should be advised of OC therapy when relevant specimens are submitted.
10. Certain endocrine- and liver-function tests and blood components may be affected by estrogen-containing OC's: a. Increased sulfobromophthalein retention. b. Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. c. Increased thyroid-binding globulin (TBG) leading to increased circulating total-thyroid hormone, as measured by protein-bound iodine (PBI), T4 by column, or T4 by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG; free T4 concentration is unaltered. d. Decreased pregnanediol excretion. e. Reduced response to metyrapone test.
Information for the Patient—See Patient Package Labeling.
Drug Interactions—Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, ampicillin and tetracycline.
Carcinogenesis—See Warnings on carcinogenic potential of OC's.
Pregnancy—Category X. See Contraindications, Warnings.
Nursing Mothers—See Warnings.
Adverse Reactions—An increased risk of these serious adverse reactions has been associated with use of OC's (see Warnings): thrombophlebitis, pulmonary embolism, coronary thrombosis, cerebral thrombosis, cerebral hemorrhage, hypertension, gallbladder disease, benign hepatomas, congenital anomalies. There is evidence of an association between the following conditions and use of OC's although additional confirmatory studies are needed: mesenteric thrombosis, neuro-ocular lesions, e.g., retinal thrombosis and optic neuritis.
The following adverse reactions have been reported in patients on OC's and are believed to be drug-related. Nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10 percent or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally. Gastrointestinal symptoms (such as abdominal cramps and bloating); breakthrough bleeding, spotting, change in menstrual flow; dysmenorrhea, amenorrhea during and after treatment, temporary infertility after discontinuance of treatment; edema; chloasma or melasma which may persist; breast changes: tenderness, enlargement, and secretion; change in weight (increase or decrease); change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature (steepening); intolerance to contact lenses.
The following adverse reactions have been reported in users of OC's, and the association has been neither confirmed nor refuted: premenstrual-like syndrome, cataracts, changes in libido, chorea, changes in appetite, cystitis-like syndrome, headache, nervousness, dizziness, hirsutism, loss of scalp hair, erythema multiforme, erythema nodosum, hemorrhagic eruption, vaginitis, porphyria.
Acute Overdose—Serious ill effects have not been reported following acute ingestion of large doses of OC's by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

LO/OVRAL® each tablet contains 0.3 mg norgestrel with 0.03 mg ethinyl estradiol.

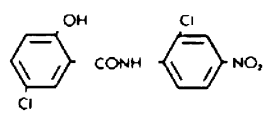
Wyeth Laboratories, Phila., Pa. 19101

Now available in the United States
From Miles Pharmaceuticals



The scolex (below) has two elongated sucking grooves; the body (in background) may have as many as 4,000 proglottids.

DESCRIPTION: NICLOCIDE (niclosamide) is an anthelmintic provided in chewable tablet form at a strength of 500 mg per tablet. Niclosamide is 2', 5-Dichloro-4'-nitrosalicylanilide. The empirical formula is $C_{13}H_8Cl_2N_2O_4$ with the following structural formula.



CLINICAL PHARMACOLOGY: NICLOCIDE inhibits oxidative phosphorylation in the mitochondria of cestodes. Both in vitro and in vivo, the scolex and proximal segments are killed on contact with the drug. The scolex of the tapeworm, loosened from the gut wall, may be digested in the intestine, and thus may not be identified in the feces even after extensive purging. The use of NICLOCIDE has not been associated with the development of anemia, leukopenia or thrombocytopenia nor have there been any effects on normal renal and hepatic functions.

INDICATIONS AND USAGE: NICLOCIDE (niclosamide) is indicated for the treatment of tapeworm infections by Taenia saginata (beef tapeworm), Diphyllobothrium latum (fish tapeworm) and Hymenolepis nana (dwarf tapeworm).

CONTRAINDICATIONS: NICLOCIDE™ Tablets are contraindicated in individuals who have shown hypersensitivity to any of its components.

PRECAUTIONS: NICLOCIDE affects the cestodes of the intestine only. It is without effect in cysticercosis.

Drug Interactions: No data are available regarding interaction of niclosamide with other drugs.

Carcinogenesis, Mutagenesis, Impairment of fertility:

Carcinogenicity Potential: Although carcinogenicity studies on niclosamide per se have not been done, long-term feeding studies on its ethanolamine salt in rats and mice did not show carcinogenicity. Mutagenicity tests have not been performed.

Pregnancy: Pregnancy Category B: Reproduction studies in rabbits and rats at doses of 25 times the human therapeutic dose and in mice at 12 times the human therapeutic dose, have revealed no evidence of impaired fertility or harm to the fetus due to niclosamide. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, the drug should be used during pregnancy only if clearly needed.

Nursing Mothers: No studies are available.

Pediatric Use: In children under 2 years of age, the safety of the drug has not been established.

ADVERSE REACTIONS: The incidence of side effects has been reported as follows: nausea/vomiting 4.1%, abdominal discomfort including loss of appetite 3.4%, diarrhea 1.6%, drowsiness, dizziness, and/or headache 1.4%, and skin rash including pruritus ani 0.3%. Other side effects listed in decreasing order of frequency were: oral irritation, fever, rectal bleeding, weakness, bad taste in mouth, sweating, palpitations, constipation, alopecia, edema of an arm, backache and irritability. There was also one instance of a transient rise in SGOT in an i.v. narcotic addict. Two cases of urticaria reported may be related to the breakdown products of the tapeworm. All of effects were mild or moderate and transitory and did not necessitate discontinuation of the treatment.

OVERDOSAGE: Insufficient data are available. In the event of overdose a fast-acting laxative and enema should be given. Vomiting should not be induced.

DOSAGE AND ADMINISTRATION:

1. Taenia saginata and Diphyllobothrium latum
   a. Adults: 4 tablets (2.0 g), chewed thoroughly in a single dose.
   b. Children weighing more than 34 kg (75 lbs): 3 tablets (1.5 g) chewed thoroughly in a single dose.
   c. Children weighing between 11 and 34 kg (25 to 75 lbs): 2 tablets (1.0 g) chewed thoroughly in a single dose.
2. Hymenolepis nana
   a. Adults: 4 tablets (2.0 g) chewed thoroughly as a single daily dose for 7 days.
   b. Children weighing more than 34 kg (75 lbs): 3 tablets (1.5 g) chewed thoroughly on the first day, then 2 tablets (1.0 g) daily for next 6 days.
   c. Children weighing between 11 and 34 kg (25 to 75 lbs): 2 tablets (1.0 g) to be chewed thoroughly on the first day, then one tablet (0.5 g) daily for next 6 days.

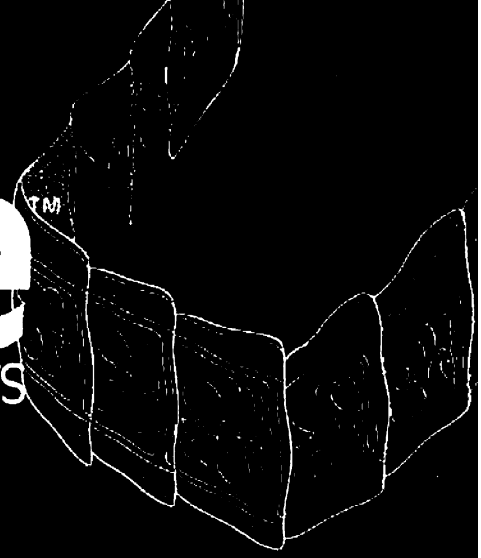
T. saginata and D. latum infections are usually due to a single adult worm and require an intermediate host in their life cycle. With Hymenolepis nana multiple infections are the rule. No intermediate host is required, both larval and adult stages of the worm may be found in the human intestine where the complete life cycle occurs. Since the drug is more effective against the

MLO-82

EW Prompt-Action

NICLOCIDE™

NICLOSAMIDE CHEWABLE TABLETS 500 MG.



safe, reliable single-dose taeniacide that eradicates beef and sh tapeworms in a single day

ighly effective prompt eniacidal action

CIDE™ (niclosamide) is consid- the drug of choice in elimi- beef tapeworm (Taenia fish or broad tapeworm bothrium latum), and dwarf rm (Hymenolepis nana) from estines. Except for the dwarf rm, which requires a seven- eatment (SEE FULL PRESCRIBING MATION BELOW), a one-day ose treatment is sufficient to e cestodes.

reaks hold of head and hain of segments

CIDE works promptly and sim- ter tablets are chewed thor- and washed down with a ter (for children tablets be pulverized and mixed with a little water). the insoluble micronized crystals act by direct contact on the tapeworm head. As soon as NICLOCIDE reaches the parasite, the scolex and upper segments are killed, thus depriving the whole chain of its hold. It is then discharged in stool either in one piece or smaller portions.

Safe and well tolerated/ little gastrointestinal mucosa irritation

NICLOCIDE has proved exceptionally well accepted by adults as well as children weighing more than 11 Kg. (25 lbs.).

Convenient one-day single-dose administration

NICLOCIDE Tablets are taken as a single dose after breakfast. Tablets must be chewed or pulverized thoroughly and washed down with a little water. No special diet or preparation is necessary except in patients who are constipated. In these cases, a thorough cleansing of the bowels may be required before treatment. The avoidance of alcohol during treatment is the only other requirement.

---

*A drastic saline purge such as magnesium sulfate or sodium sulfate should be given two hours after the NICLOCIDE dose if it is required that the tapeworms be expelled rapidly and in one piece.

†In infections with beef tapeworm (T. saginata) and fish tapeworm (D. latum) one single dose is sufficient. For infections with dwarf tapeworm (H. nana) a seven-day treatment is recommended (SEE FULL PRESCRIBING INFORMATION ON THESE PAGES).

mature than the larval stage, therapy must be extended over several days to cover all stages of maturation.

Patients with H. nana must be instructed to observe strict personal and environmental hygiene to avoid autoinfection with this parasite.

NICLOCIDE™ must be thoroughly chewed and then swallowed with a little water. No special dietary restrictions are necessary before or after treatment. The best time to take the drug is after a light meal (e.g., breakfast). A mild laxative may be desirable in constipated patients to achieve a normal bowel movement.

Young children should have the tablets crushed to a fine powder and mixed with a small amount of water to form a paste.

NICLOCIDE has a vanilla taste which is not unpleasant to most persons.

NICLOCIDE is suitable for administration on an ambulatory or outpatient basis.

Follow-up:

As the vermicidal action of NICLOCIDE renders the tapeworm, especially the scolex and proximal segments, vulnerable to destruction during their passage through the gut, it is not always possible to identify the scolex in stools. The sooner the tapeworm is passed and examined after treatment, the better the chance of identification of the scolex. Segments and/or ova of beef or fish tapeworm may be present in the stool for up to 3 days after therapy. Persistent T. saginata or D. latum segments and/or ova on the seventh day post therapy indicate failure. A second identical course of treatment may be given at that time.

No patient should be considered cured unless the stool has been negative for a minimum of three months.

HOW SUPPLIED: NICLOCIDE is available as round, light yellow chewable tablets, scored on one side, embossed with the word Miles and number 721, each containing 500 mg of niclosamide, and is supplied in boxes of 4 tablets.

Storage Conditions: Store below 86°F (30°C), avoid freezing.

Manufactured by
Bayvet Division Cutter Laboratories, Inc.
Shawnee, Kansas 66201

Distributed by
Miles Pharmaceuticals
Division of Miles Laboratories, Inc.
West Haven, Connecticut 06516

PD100551 18612 Made and printed in USA April 1982

NICLOCIDE™

Drug of Choice for Eliminating Tapeworms

MILES
Miles Pharmaceuticals

A CONTINUING FORCE IN THERAPEUTIC PROGRESS

A NEW AGE IN THE CONTROL OF ANGINA

(R)

(NIFEDIPINE) *Capsules 10 mg*

PROCARDIA is the beginning of a new age in the treatment of angina.

The Calcium Age.

It is now known that calcium ions, working at the cellular level, regulate the degree of vasoconstriction and thereby play a critical role in the angina attack.

PROCARDIA acts at the cell membrane to check the inward flow of calcium ions to the contractile process in the arterial cell.

Through this action, PROCARDIA manages:

vasospastic angina, by preventing coronary artery spasm and increasing myocardial O_2 supply

—classical effort-associated angina, by dilating peripheral arteries to reduce afterload and myocardial O_2 demand

—mixed angina, which involves elements of vasospastic and effort-associated angina

Like beta-blockers, PROCARDIA reduces myocardial O_2 demand. But unlike these agents, PROCARDIA also increases myocardial O_2 supply to both normal and post-ischemic areas of the myocardium by preventing coronary artery spasm.

PROCARDIA

THE FIRST ORAL CALCIUM CHANNEL BLOCKER

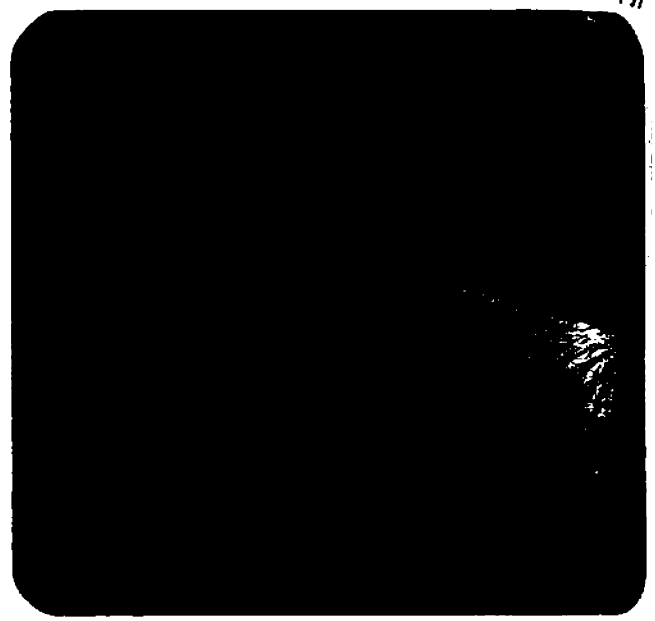
PROCARDIA®
(NIFEDIPINE) *Capsules 10 mg*

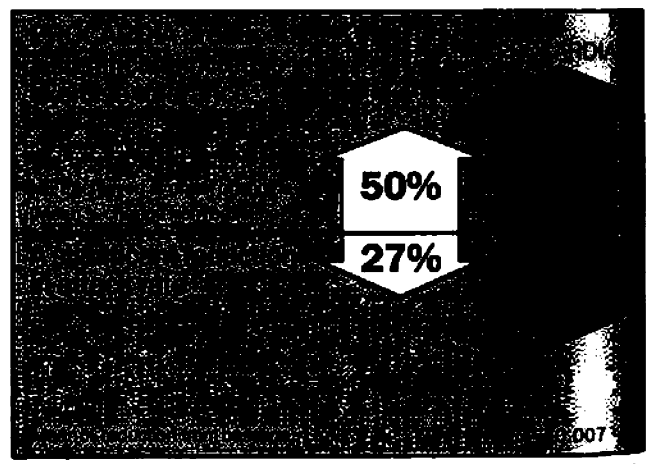
PROVEN EFFECTIVE ACROSS THE SPECTRUM OF ANGINA

Contemporary medical opinion holds that the pathophysiology of angina is a spectrum ranging from pure, fixed atherosclerotic lesion to pure coronary artery spasm. Many patients, however, are believed to have a combination of both lesion and spasm.[2,3]

Angina due to pure fixed lesion can be prevented by reducing oxygen demand. Angina due to coronary artery spasm can be treated by preventing the spasm itself, thereby increasing oxygen supply. With this new understanding of angina, optimal antianginal therapy should provide this dual action: increasing O_2 supply while reducing O_2 demand.

In effort angina*
(when symptomatic despite conventional therapy)



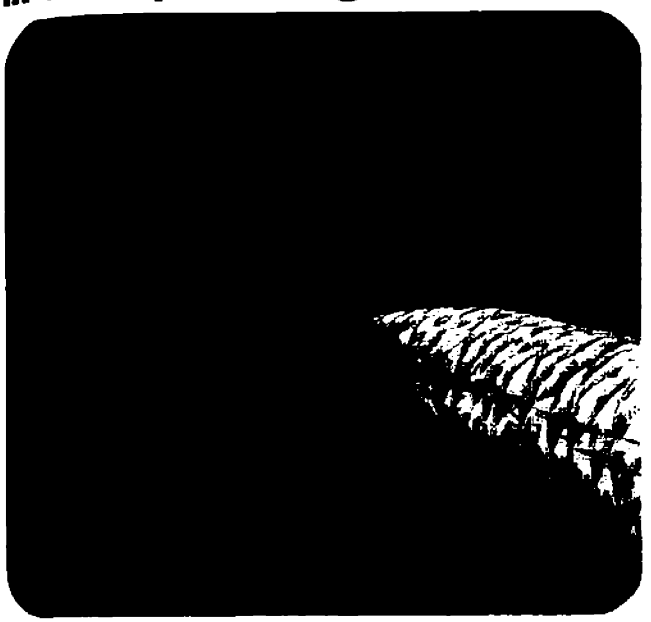


Double-blind, placebo-controlled, crossover 20-week study of 32 patients (27 evaluated for attack rate; 19 for exercise tolerance). Mean PROCARDIA dosage: 51 mg/day.

*In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients are incomplete.

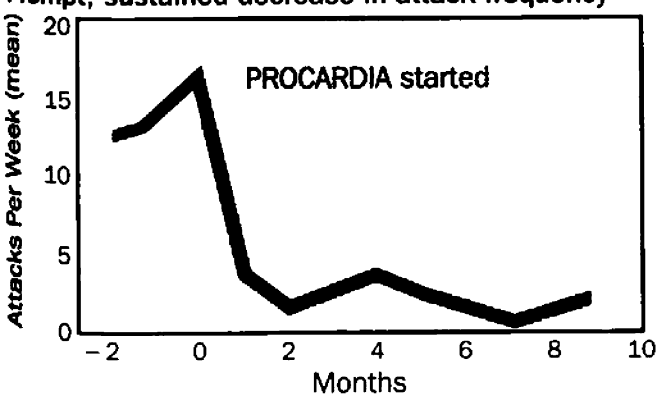
Please see PROCARDIA Brief Summary on last page.

In vasospastic angina



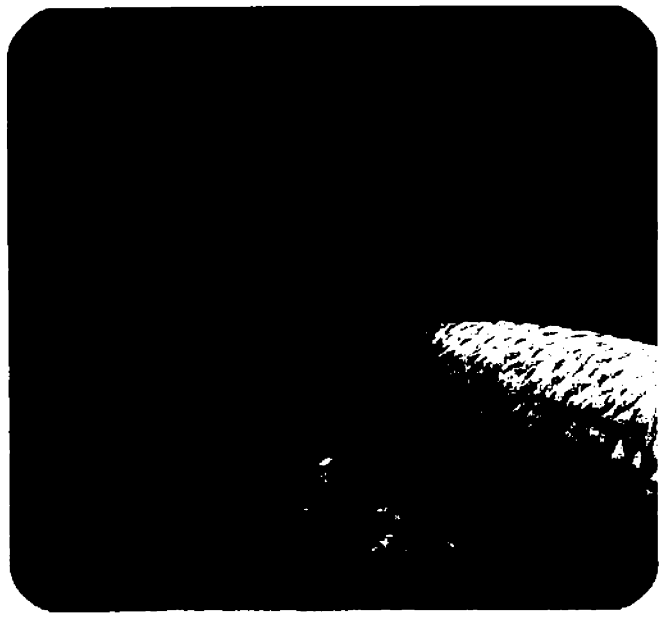
PROCARDIA eliminated attacks in 63% of patients[5]

Prompt, sustained decrease in attack frequency[5]



Long-term, open study of 127 patients unresponsive to beta blockers and/or nitrates with symptoms of myocardial ischemia and demonstrated coronary artery spasm. PROCARDIA dosage: 40 to 160 mg/day.

In mixed angina (fixed lesion and spasm)



PROCARDIA reduced attack rate[6]
Mean number of attacks per week

N = 417

18.6 baseline

5.4 PROCARDIA

71% reduction

P <0.00005

PROCARDIA reduced nitroglycerin use[6]
Mean number of tablets per week

N = 353

25.7 baseline

8.1 PROCARDIA

68% reduction

P <0.00005

Studies of patients with mixed angina characterized by pain at rest and effort. Most patients (89%) were initiated on nitrate and/or beta blocker therapy but remained symptomatic. Minimum duration of nifedipine treatment two months. Nifedipine dosage: 30 to 120 mg/day.

PROCARDIA®
THE FIRST ORAL CALCIUM CHANNEL BLOCKER

THE FIRST ORAL CALCIUM CHANNEL BLOCKER FOR THE MANAGEMENT OF ANGINA

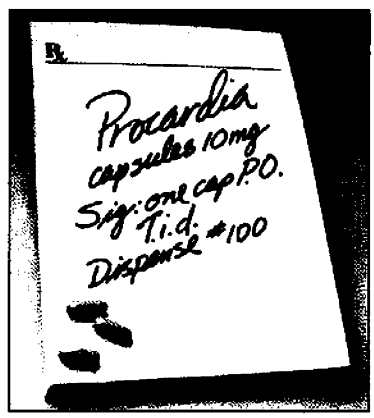
PROCARDIA®
(NIFEDIPINE) *Capsules 10 mg*

Proven effective when used alone.

Enhanced effectiveness when combined with beta blockers.

Convenient dosing

Start with:	1	10-mg capsule *t.i.d.*
Titrate to:	2	10-mg capsules *t.i.d.*
Titrate to:	3	10-mg capsules *t.i.d.*



For most patients, titrate over 7 to 14 days, using the patient's blood pressure response, attack frequency, sublingual nitroglycerin intake and activity level as a guide. Titration may be more rapid (e.g., 3 days) if symptoms warrant and the patient is observed closely. Maximum dose: 180 mg/day.

References

1. Lichtlen PR, Engel H-I, Wolf R, et al: Regional myocardial blood flow in patients with coronary artery disease after nifedipine. In Lichtlen PR, Kimura E, Taira N (eds): *International Adalat® Panel Discussion: New Experimental and Clinical Results*. Tokyo, Excerpta Medica, 1978, pp 69–85.
2. Masani A, Chierchia S: Angina pectoris—a new dimension, a new approach: Part 2. *Primary Cardiol* 6:123–136, October 1980.
3. Braunwald E: *Introduction: New Concepts in Ischemic Heart Disease: The Role of Coronary Artery Spasm*. New York, Science & Medicine, Inc, 1980, p 1.
4. Mueller HS, Chahine RA: Interim report of multicenter double-blind, placebo-controlled studies of nifedipine in chronic stable angina. *Am J Med* 71:645–657, October 1981.
5. Antman E, Muller J, Goldberg S, et al: Nifedipine therapy for coronary-artery spasm: experience in 127 patients. *N Engl J Med* 302:1269–1273, June 5, 1980.
6. Braunwald E (moderator): Procardia® (nifedipine) in clinical practice. Presented at symposium following the Thirty-First Annual Scientific Session of the American College of Cardiology, Atlanta, Georgia, April 29, 1982.

PROCARDIA® CAPSULES

For Oral Use

(nifedipine)

BRIEF SUMMARY

INDICATIONS AND USAGE: I. Vasospastic Angina: PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort-Associated Angina): PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta-blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Increased Angina/Beta Blocker Withdrawal: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients usually receiving a beta blocker have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate the peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Pregnancy: Category C.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing, each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA Capsule contains 10 mg of nifedipine. PROCARDIA Capsules are supplied in amber glass bottles of 100 capsules (NDC 0069-2600-66).

The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

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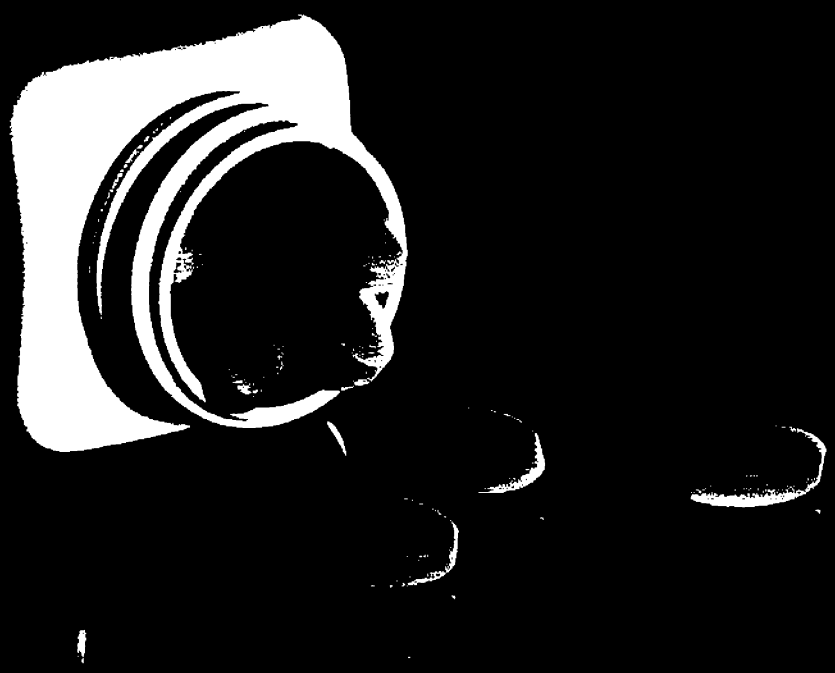
ibuprofen, Upjohn

600 mg Tablets



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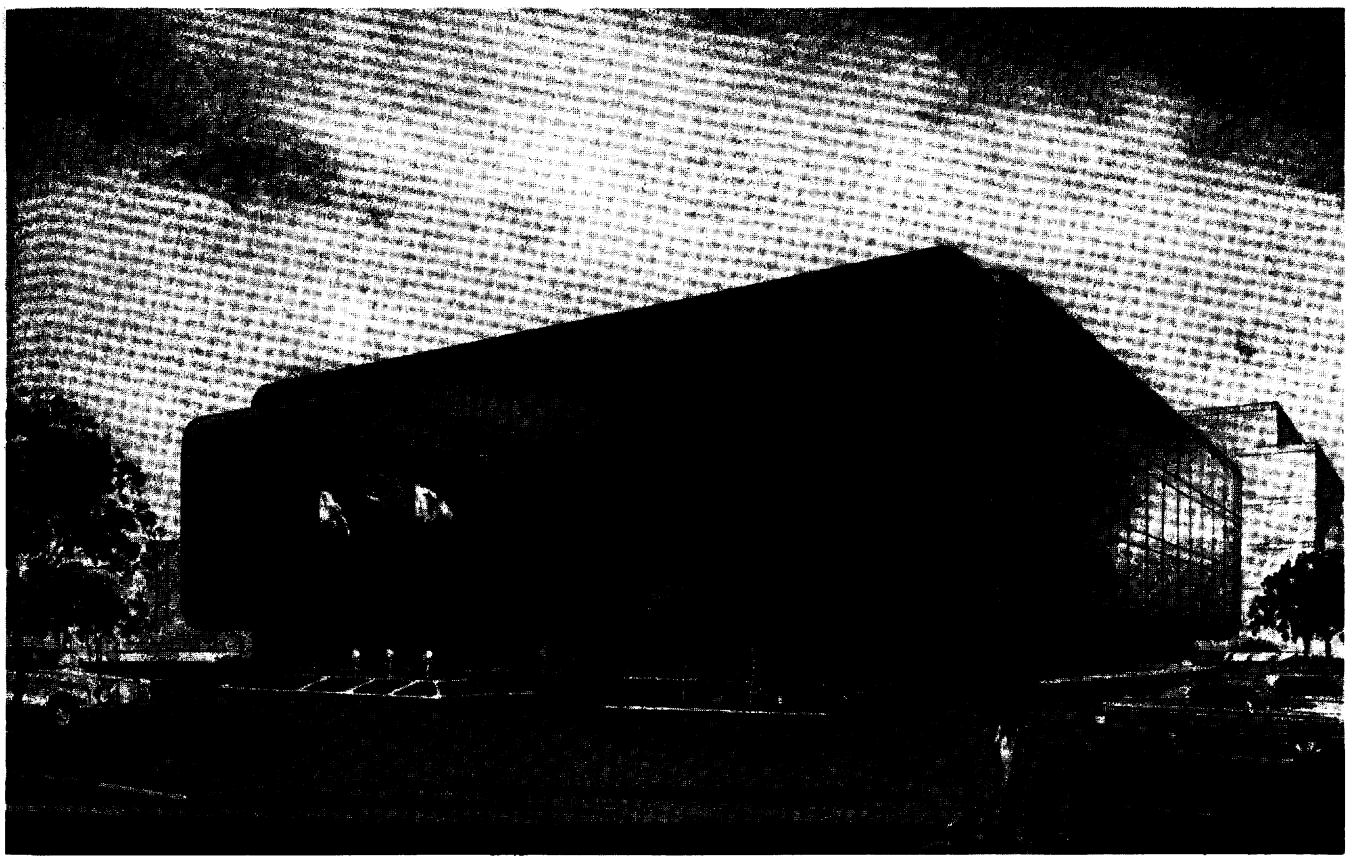

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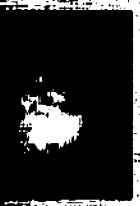
WE HAVE A SOLUTION FOR A DIFFICULT UROLOGICAL PROBLEM

The Problem

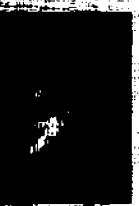
MPTOMS:

EARLY INTERSTITIAL CYSTITIS



- ☐ irritative voiding symptoms
- ☐ suprapubic pain
- ☐ functional bladder capacity reduced
- ☐ anatomical bladder capacity:
  - EARLY — normal
  - CLASSICAL — reduced

CLASSICAL INTERSTITIAL CYSTITIS



- ☐ vesical mucosa:
  - EARLY — normal appearing
  - CLASSICAL — ulcerated, scarred
- ☐ submucosal vesical hemorrhages observed following second overdistension

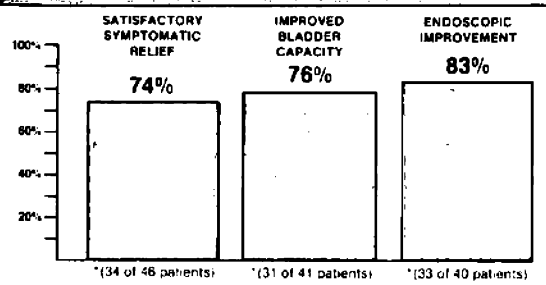
AGNOSIS: INTERSTITIAL CYSTITIS

The Solution

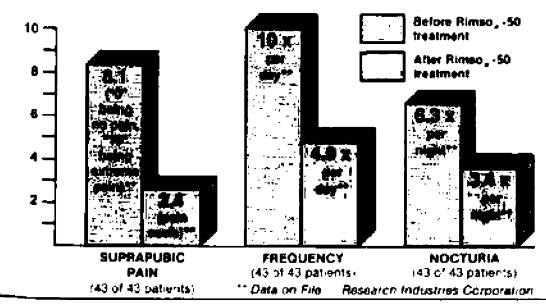
Rimso-50®

brand of

STERILE AND PYROGEN-FREE DIMETHYL SULFOXIDE



*STEWART, B.H. et al., J. Urol. 36:116, 1976



** Data on File Research Industries Corporation

FOR FURTHER INFORMATION

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1847 West 2300 South
Salt Lake City, Utah 84119
Toll-Free 1-800-453-8432

Name

Address

City State Zip

Rimso-50®

(dimethyl sulfoxide)

50% w/w aqueous solution

INDICATIONS AND USAGE: Rimso-50® (dimethyl sulfoxide) is indicated for the symptomatic relief of patients with interstitial cystitis. Rimso-50® has not been approved as being safe and effective for any other indication. There is no clinical evidence of effectiveness of dimethyl sulfoxide in the treatment of bacterial infections of the urinary tract.

CONTRAINDICATIONS: None known.

WARNINGS: Dimethyl sulfoxide can initiate the liberation of histamine and there has been occasional hypersensitivity reaction with topical administration of dimethyl sulfoxide. This hypersensitivity has been reported in one patient receiving intravesical Rimso-50®. The physician should be cognizant of this possibility in prescribing Rimso-50®. If anaphylactoid symptoms develop, appropriate therapy should be instituted.

PRECAUTIONS: Changes in the refractive index and lens opacities have been seen in monkeys, dogs and rabbits given high doses of dimethyl sulfoxide chronically. Since lens changes were noted in animals, full eye evaluations, including slit lamp examinations, are recommended prior to and periodically during treatment. Approximately every six months patients receiving dimethyl sulfoxide should have a biochemical screening, particularly liver and renal function tests, and complete blood count.

Intravesical instillation of Rimso-50® may be harmful to patients with urinary tract malignancy because of dimethyl sulfoxide-induced vasodilation. Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications.

Pregnancy Category C. Dimethyl sulfoxide caused teratogenic responses in hamsters, rats, and mice when administered intraperitoneally at high doses (2.5-12 gm/kg). Oral or topical doses of dimethyl sulfoxide did not cause problems of reproduction in rats, mice and hamsters. Topical doses (5 gm/kg first two days, then 2.5 gm/kg - last eight days) produced terata in rabbits, but in another study, topical doses of 1.1 gm/kg days 3 through 16 of gestation failed to produce any abnormalities. There are no adequate and well controlled studies in pregnant women. Dimethyl sulfoxide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dimethyl sulfoxide is administered to a nursing woman.

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: A garlic-like taste may be noted by the patient within a few minutes after instillation of Rimso-50® (dimethyl sulfoxide). This taste may last several hours and because of the presence of metabolites, an odor on the breath and skin may remain for 72 hours.

Transient chemical cystitis has been noted following instillation of dimethyl sulfoxide. The patient may experience moderately severe discomfort on administration. Usually this becomes less prominent with repeated administration.

DOSAGE AND ADMINISTRATION: Instillation of 50 ml of Rimso-50® (dimethyl sulfoxide) directly into the bladder may be accomplished by catheter or asepto syringe and allowed to remain for 15 minutes. Application of an analgesic lubricant gel such as lidocaine jelly to the urethra is suggested prior to insertion of the catheter to avoid spasm. The medication is expelled by spontaneous voiding. It is recommended that the treatment be repeated every two weeks until maximum symptomatic relief is obtained. Thereafter, time intervals between therapy may be increased appropriately.

Administration of oral analgesic medication or suppositories containing belladonna and opium prior to the instillation of Rimso-50® can reduce bladder spasm.

In patients with severe interstitial cystitis with very sensitive bladders, the initial treatment and possibly the second and third (depending on patient response) should be done under anesthesia. (Saddle block has been suggested).

HOW SUPPLIED:

Bottles contain 50 ml of sterile and pyrogen-free Rimso-50® (50% w/w dimethyl sulfoxide aqueous solution).

Dimethyl sulfoxide is clear and colorless.

Protect from strong light.

Store at room temperature (15° to 30° C).

Do not autoclave.

NDC #0433-0433-05

*Stewart, B.H., et al. J. Urol. 36:116, 1976

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brand of

STERILE AND PYROGEN-FREE DIMETHYL SULFOXIDE

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Available in:

10 ml ampules, 10 ampules/case
70 ml bottles, 6 bottles/case
70 ml multi-dose containers, 6 bottles/case

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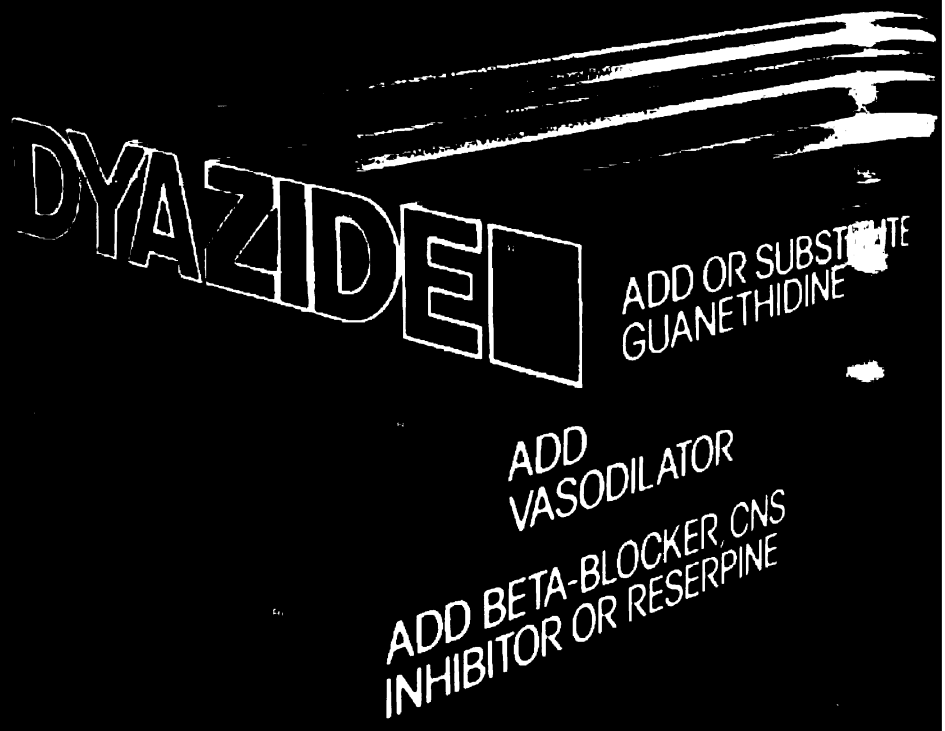

Each capsule contains 50 mg. of Dyrenium® (brand of triam... and 25 mg. of hydrochlorothi...

EFFECTIVE STEP 1 DIURETIC THERAPY (when the combination represents previously titrated dosage)

...y consists of an initial phase (a diuretic ... a titration phase (dosage adjustment and/or addition of a K^+ supplement or K^+-sparing agent), and a maintenance phase (a diuretic alone or in combination with a K^+ supplement or K^+-sparing agent).

Serum K^+ and BUN should be checked periodically (see Warnings).

Before prescribing, see complete prescribing information in SK&F Co. literature or *PDR*. The following is a brief summary.

* **WARNING**
This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with Dyazide, but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis and of impotence have been reported with the use of 'Dyazide', although a causal relationship has not been established.

Supplied: Bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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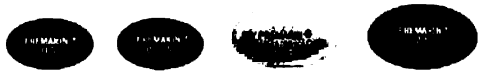

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†Conjugated Estrogens Tablets have been evaluated as probably effective for postmenopausal osteoporosis.

**There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms.

Please see following page for Brief Summary of Prescribing Information.

Y PHYSICIANS WHO CARE.

BRIEF SUMMARY
(FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULAR)

PREMARIN® Brand of Conjugated Estrogens Tablets, U.S.P.

PREMARIN® Brand of Conjugated Estrogens, U.S.P. Vaginal Cream in a nonliquefying base

1. ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA.
Three independent case control studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case control studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semiannual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration; it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equiestrogenic doses.
2. ESTROGENS SHOULD NOT BE USED DURING PREGNANCY
The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a non-steroidal estrogen, have an increased risk of developing in later life a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1000 exposures. Furthermore, a high percentage of such exposed women (from 30 to 90 percent) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb reduction defects. One case control study estimated a 4.7-fold increased risk of limb reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb reduction defects in exposed fetuses is somewhat less than 1 per 1000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (Conjugated Estrogens, U.S.P.) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equilin and 17α-dihydroequilin, together with smaller amounts of 17α-estradiol, equilenin, and 17α-dihydroequilenin as salts of their sulfate esters.

INDICATIONS: Based on a review of PREMARIN Tablets by the National Academy of Sciences - National Research Council and/or other information, FDA has classified the indications for use as follows
Effective: 1. Moderate to severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms, and they should not be used to treat such conditions.)
2. Atrophic vaginitis
3. Kraurosis vulvae
4. Female hypogonadism
5. Female castration
6. Primary ovarian failure
7. Breast cancer (for palliation only) in appropriately selected women and men with metastatic disease.
8. Prostatic carcinoma – palliative therapy of advanced disease.
9. Postpartum breast engorgement – Although estrogens have been widely used for the prevention of postpartum breast engorgement, controlled studies have demonstrated that the incidence of significant painful engorgement in patients not receiving such hormonal therapy is low and usually responsive to appropriate analgesic or other supportive therapy. Consequently, the benefit to be derived from estrogen therapy for this indication must be carefully weighed against the potential increased risk of puerperal thromboembolism associated with the use of large doses of estrogens.
PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING)
"Probably" effective: For estrogen deficiency-induced osteoporosis, and only when used in conjunction with other important therapeutic measures such as diet, calcium, physical therapy, and good general health-promoting measures. Final classification of this indication requires further investigation.

INDICATIONS: PREMARIN (Conjugated Estrogens, U.S.P.) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae. PREMARIN Vaginal Cream HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).
CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen dependent neoplasia. 3. Known or suspected pregnancy (See Boxed Warning). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).
WARNINGS: Long term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. There are now reports that estrogens increase the risk of carcinoma of the endometrium in humans. (See Boxed Warning.) At the present time there is no satisfactory evidence that estrogens given to postmenopausal women increase the risk of cancer of the breast, although a recent study has raised this possibility. There is a need for caution in prescribing estrogens for women with a strong family history of breast cancer or who have breast nodules, fibrocystic disease, or abnormal mammograms. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.
Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement; it has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.
Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.
PRECAUTIONS: Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention, such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Preexisting uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not complete.
The following changes may be expected with larger doses of estrogen:
a. Increased sulfobromophthalein retention.
b. Increased prothrombin and factors VII, VIII, IX and X; decreased antithrombin 3, increased norepinephrine-induced platelet aggregability.
c. Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T4 by column, or T4 by radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG; free T4 concentration is unaltered.
d. Impaired glucose tolerance
e. Decreased pregnanediol excretion
f. Reduced response to metyrapone test
g. Reduced serum folate concentration.
h. Increased serum triglyceride and phospholipid concentration
As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.
ADVERSE REACTIONS: The following have been reported with estrogenic therapy: including oral contraceptives: breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; premenstrual-like syndrome; amenorrhea during and after treatment; increase in size of uterine fibromyomata; vaginal candidiasis; change in cervical erosion and in degree of cervical secretion; cystitis-like syndrome; tenderness, enlargement, secretion (of breasts); nausea, vomiting; abdominal cramps; bloating; cholestatic jaundice; chloasma or melasma which may persist when drug is discontinued; erythema multiforme; erythema nodosum; hemorrhagic eruption; loss of scalp hair; hirsutism; steepening of corneal curvature; intolerance to contact lenses; headache; migraine; dizziness; mental depression; chorea; increase or decrease in weight; reduced carbohydrate tolerance; aggravation of porphyria; edema; changes in libido.
ACUTE OVERDOSAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSAGE AND ADMINISTRATION:
PREMARIN® Brand of Conjugated Estrogens Tablets, U.S.P.
1. *Given cyclically for short-term use only.* For treatment of moderate to severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 to 1.25 mg or more daily).
The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.
Administration should be cyclic (*e.g.*, three weeks on and one week off).
Attempts to discontinue or taper medication should be made at three to six month intervals.
2. *Given cyclically:* Female hypogonadism. Female castration. Primary ovarian failure. Osteoporosis.
Female hypogonadism – 2.5 to 7.5 mg daily, in divided doses for 20 days, followed by a rest period of 10 days' duration. If bleeding does not occur by the end of this period, the same dosage schedule is repeated. The number of courses of estrogen therapy necessary to produce bleeding may vary depending on the responsiveness of the endometrium.
If bleeding occurs before the end of the 10 day period, begin a 20 day estrogen-progestogen cyclic regimen with PREMARIN (Conjugated Estrogens Tablets, U.S.P.), 2.5 to 7.5 mg daily in divided doses, for 20 days. During the last five days of estrogen therapy, give an oral progestin. If bleeding occurs before this regimen is concluded, therapy is discontinued and may be resumed on the fifth day of bleeding.
Female castration and primary ovarian failure – 1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.
Osteoporosis (to retard progression) – 1.25 mg daily, cyclically.
3. *Given for a few days:* Prevention of postpartum breast engorgement – 3.75 mg every four hours for five doses, or 1.25 mg every four hours for five days.
4. *Given chronically:* Inoperable progressing prostatic cancer – 1.25 to 2.5 mg three times daily.
Inoperable progressing breast cancer in appropriately selected men and postmenopausal women – 10 mg three times daily for a period of at least three months.
Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.
PREMARIN® Brand of Conjugated Estrogens, U.S.P. Vaginal Cream
Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.
The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.
Administration should be cyclic (*e.g.*, three weeks on and one week off).
Attempts to discontinue or taper medication should be made at three to six month intervals.
Usual dosage range: 2 to 4 g daily, intravaginally or topically, depending on the severity of the condition.
Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.
HOW SUPPLIED: PREMARIN (Conjugated Estrogens, U.S.P.) No. 865 – Each *purple* tablet contains 2.5 mg in bottles of 100 and 1,000. No. 866 – Each *yellow* tablet contains 1.25 mg in bottles of 100 and 1,000. Also in unit dose package of 100. No. 867 – Each *red* tablet contains 0.625 mg in bottles of 100 and 1,000. Also in unit dose package of 100. No. 868 – Each *green* tablet contains 0.3 mg in bottles of 100 and 1,000.
PREMARIN (Conjugated Estrogens, U.S.P.) Vaginal Cream – No. 872 – Each gram contains 0.625 mg Conjugated Estrogens, U.S.P. (Also contains cetyl esters wax, cetyl alcohol, white wax, glyceryl monostearate, propylene glycol monostearate, methyl stearate, phenylethyl alcohol, sodium lauryl sulfate, glycerin, and mineral oil.)
Combination package – Each contains Net Wt. 1½ oz. (42.5 g) tube with one calibrated plastic applicator.
Also Available – Refill package. Each contains Net Wt. 1½ oz. (42.5 g) tube. 7834/282

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(Continued on Page 48)

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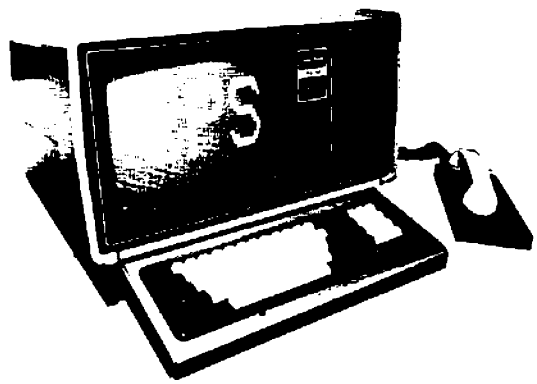

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(Continued from Page 44)

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Responsible physicians know that despite sound medical judgment and specialized skills, their prognoses are often subject to uncertainty.

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Responsible medical malpractice insurers, like The Doctors' Company, know that their policyholders' long-range interests are best protected by financial strength and solvency.

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Operations Office, 13th International Cancer Congress, Fourth and Blanchard Building, Suite 1800, Seattle, WA 98121. (206) 621-9440.

September 10—**Leonard Memorial Lecture: Endocrine Day.** Seattle. Friday. U/W South Campus Center. Contact: U/W.

September 10-11—**Advanced Cardiac Life Support.** Seattle. Friday-Saturday. U/W Health Sciences Building. Contact: U/W.

September 10-11—**Short-term Group Psychotherapy.** Seattle. Friday-Saturday. Virginia Mason Medical Center. Contact: VMMC.

September 16-17—**Plastic Repair and Wound Management.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

September 16-18—**(WYOMING) Cytology Continuing Education Workshop.** Jackson. Thursday-Saturday. Contact: CME Harborview.

September 23-25—**Cytology Continuing Education Workshop.** Renton. Thursday-Saturday. Valley General Hospital. Contact: CME Harborview.

September 23-25—**Advances in Internal Medicine.** Seattle. Thursday-Saturday. Westin Hotel. Contact U/W.

September 24—**Pathology Day.** Seattle. Friday. U/W Health Sciences Building. Contact: U/W.

September 24-25—**Immediate Care of Sick and Injured.** Seattle. Friday-Saturday. U/W Health Sciences Center. Contact: U/W.

September 30-October 1—**Neuroendrocrinology.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

October 1-2—**Otolaryngology for Non-Otolaryngologists.** Seattle. Friday-Saturday. U/W Health Sciences Building. Contact: U/W.

October 7-10—**Annual Meeting, Washington State Medical Association.** Yakima. Thursday-Sunday. Yakima Convention Center, The Towne Plaza, and The Holiday Inn. Contact: Marcia Wahlman, Convention Coordinator, Washington State Medical Association, 2033 Sixth Avenue, Suite 900, Seattle, WA 98121. (206) 623-4801.

October 8-9—**Annual Cancer Conference: Symptom Management in the Cancer Patient.** Seattle. Friday-Saturday. Virginia Mason Medical Center. Contact: VMMC.

October 15-16—**The Insulin Pump in Clinical Practice.** Seattle. Friday-Saturday. Virginia Mason Medical Center. Contact: VMMC.

October 21-22—**Nosocomial Infections and Herpes/Hepatitis.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

October 22—**Gynecologic Surgery.** Seattle. Friday. Virginia Mason Medical Center. Contact: VMMC.

October 22-23—**Care and Rehabilitation of the Injured Wrist.** Seattle. Friday-Saturday. U/W Health Sciences Building. Contact: U/W.

October 28-29—**Office Gynecology for Primary Physicians.** Seattle. Thursday-Friday. Park Hilton. Contact: U/W.

November 4-5—**Current Concepts in Drug Therapy.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

November 11-12—**Topics in Emergency Medicine.** Seattle. Thursday-Friday. Sea-Tac Marriott Hotel. Contact: Heidi Hilby, Executive Secretary, Washington Chapter, American College of Emergency Physicians, 2033 Sixth Avenue, Suite 900, Seattle, WA 98121. (206) 623-4801.

November 12—**Eye Care in General Practice.** Seattle. Friday. Virginia Mason Medical Center. Contact: VMMC.

November 12-13—**Diabetes. Seattle.** Friday-Saturday. U/W Health Sciences Building. Contact: U/W.

November 13-14—**Medicine and Religion.** Seattle. Saturday-Sunday. U/W Health Sciences Building. Contact: U/W.

November 18-19—**Psychiatric Emergencies.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

November 19—**Neuroophthalmology Seminar.** Seattle. Friday. Virginia Mason Medical Center. Contact: VMMC.

December 2-3—**Surgical Aspects of Lung Disease.** Seattle. Thursday-Friday. Sheraton Hotel. Contact: U/W.

December 3—**Practical Pediatrics.** Seattle. Friday. Virginia Mason Medical Center. Contact: VMMC.

December 4—**Orthopaedics for Attorneys.** Seattle. Saturday. Sheraton Hotel: Contact: U/W.

December 6-7—**American College of Physicians MKSAP IV.** Seattle. Monday-Tuesday. U/W Health Sciences Building. Contact: U/W.

December 9-10—**Aging and Elderly.** Seattle. Friday-Saturday. Sheraton Hotel. Contact: U/W.

January 13-14—**Sex and the Family.** Seattle. Friday-Saturday. Westin Hotel. Contact: U/W.

January 20-21—**Cytology.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

January 21-23—**Ophthalmic Plastic and Reconstructive Surgery.** Seattle. Friday-Sunday. Sheraton Hotel. Contact: Marcia Wahlman, Executive Secretary, Washington State Academy of Ophthalmology, 2033 Sixth Avenue, Suite 900, Seattle, WA 98121. (206) 623-4801.

January 27-28—**Beta Blockers and Calcium Antagonists.** Seattle. Thursday-Friday. Sheraton Hotel. Contact: U/W.

January 29-30—**Benefits and Problems of Exercise.** Seattle. Saturday-Sunday. Swedish Hospital. Contact: U/W.

February 3-4—**Ultrasound/Echocardiography.** Seattle. Wednesday-Thursday. U/W Health Sciences Building. Contact: U/W.

February 14-18—**(IDAHO) Sun Valley Primary Care Conference.** Sun Valley. Monday-Friday. Sun Valley Lodge. Contact: Marilyn R. Carlson, Continuing Education, Northwest Hospital, 1551 North 115th, Seattle, WA 98133. (206) 364-0500, ext. 1737.

February 17-18—**Soft Tissue Surgery.** Seattle. Wednesday-Thursday. U/W Health Sciences Building. Contact: U/W.

February 24-25—**Contemporary Clinical Neurology.** Seattle. Thursday-Friday. Virginia Mason Medical Center. Contact: VMMC.

March 4-5—**High-Risk Infants of the 1980s.** Seattle. Wednesday-Friday. Children's Orthopedic Hospital. Contact: U/W.

March 10-11—**Nutrition and Bone Metabolism.** Seattle. Wednesday-Thursday. Sheraton Hotel. Contact: U/W.

March 18-19—**Recent Developments in Occupational Medicine.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

March 25-26—**Advanced Cardiac Life Support.** Seattle. Thursday-Friday. U/W Health Sciences Building. Contact: U/W.

April 1-2—**Compensation Law/Public Policy/Back Pain.** Seattle. Thursday-Friday. Sheraton Hotel. Contact: U/W.

April 8-9—**Management of Obesity. Seattle.** Thursday-Friday. Sheraton Hotel. Contact: U/W.

April 11-22—**Rehabilitation Medicine Review.** Seattle. Sunday-Thursday. Sheraton. Contact: U/W.

April 14-15—**Vascular Disease/Primary MDs.** Seattle. Wednesday-Thursday. U/W Health Sciences Building. Contact: U/W.

April 22-24—**Office Laboratory Diagnosis for the Clinician.** Seattle. Thursday-Saturday. U/W Health Sciences Building. Contact: U/W.

April 28-29—**Financial Planning for Physicians.** Seattle. Wednesday-Thursday. Sheraton Hotel. Contact: U/W.

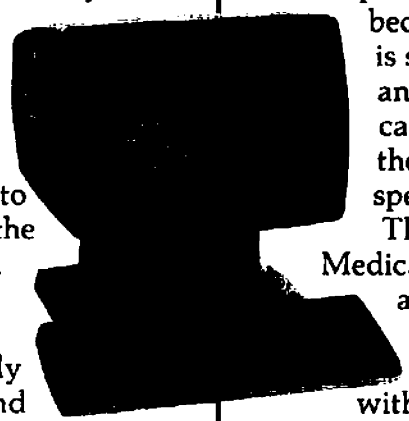
May 6-7—**Advances in Behavioral Medicine.** Seattle. Thursday-Friday. Swedish Hospital. Contact: U/W.

May 13—**Medical Alumni Day.** Seattle. Thursday. U/W Health Sciences Building. Contact: U/W.

(Continued on Page 56)

Why you should buy your medical computer system from a specialist instead of a general practitioner.

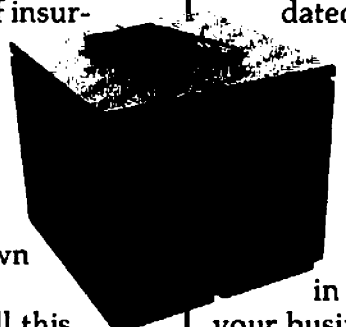
At Westland Medical Systems we do not try to be all things to all people.



We knew when we started that if we were going to be effective in the area of medical systems we would have to work intensively with doctors and only with doctors.

Our System, The Westland Medical System, was developed, tested and proven in offices like yours.

Before we ever designed our system we totally immersed ourselves in the business side of your practice. We learned how crippling paperwork can be. How delays in the preparation of insurance forms can seriously affect your cash flow. We learned how important it is for you to have your finger on your own financial pulse.



The result of all this learning was the Westland Medical System.

The Westland Medical System completely prepares all necessary insurance forms quickly and accurately so your turnaround time is as short as possible. And because our system is so flexible insurance information can be formatted to the needs of your specific practice.

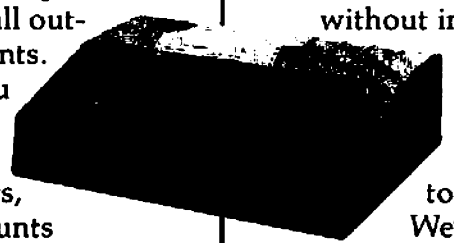
The Westland Medical System issues all your patient statements and provides you with complete information about all outstanding accounts. It also gives you a number of valuable management reports, including accounts receivable age analysis, departmental revenue, and doctor productivity. All reports are available and updated on a daily basis.

The Westland Medical System is even available with appointment scheduling.

The Westland Medical System is, in short, a solution to your business problems. But unlike some solutions, which are more complex than the problems they are designed to solve, the Westland Medical System is amazingly simple to operate.

It does not require any special personnel. Instead of being written in Computerese it is written in easy to understand english sentences. Simple, step-by-step instructions direct the operator from the simplest (or most general) to the most detailed part of any task.

Your System can be set up and your people trained, in a matter of days. Best of all, this can be accomplished without interfering with the course of your work.



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USMA ANNUAL MEETING

SPECIAL SESSION NO. 1 — 8:00 am
THURSDAY, SEPTEMBER 16, 1982

CARCINOMA OF THE BREAST

Problems of Differential Diagnosis of Controversial Breast Lesions
RAFFAELE LATTES, MD
Columbia-Presbyterian Medical Center
New York, New York

Primary Management of Carcinoma of the Breast
WILLIAM LAURENCE DONEGAN, MD
Medical College of Wisconsin
Milwaukee, Wisconsin

Adjuvant Treatment of Carcinoma of the Breast with an Emphasis on the Role of Estrogen Receptors
BARTH HOOGSTRATEN, MD
Medical Director
Cancer Treatment Center
Bethesda Hospital
Cincinnati, Ohio

Prophylactic Mastectomy and Breast Reconstruction Following Mastectomy
DONALD F. TEAL, MD
Eugene, Oregon

SPECIAL SESSION NO. 2 — 8:00 am
THURSDAY, SEPTEMBER 16, 1982

NEW DEVELOPMENTS IN CARDIOVASCULAR DISEASE

Calcium Channel Blockade in the Management of Cardiovascular Diseases
ELLIOTT M. ANTMAN, MD
Brigham-Women's Hospital
Harvard Medical School
Boston, Massachusetts

Prediction of Risk of Cardiovascular Morbidity and Mortality
SHAHBUDEN RAHEMTOOLA, MD
University of Southern California
Los Angeles, California

Angioplasty of Renal and Visceral Arterial Disease
ERNEST J. RING, MD
Professor of Radiology
Director of Interventional Radiology
University of California
San Francisco, California

Heart Transplantation
STUART W. JAMIESON, MD
Assistant Professor of Cardiovascular Surgery
Director of Cardiac Transplantation
Stanford University School of Medicine
Stanford, California

FIFTH ANNUAL SKAGGS LUNCHEON

12:00 NOON

"WHAT'S NEW IN MY SPECIALTY"

Provocative brief overview of innovations in six specialty areas presented by guest speakers from morning sessions.

UTAH STATE MEDCIAL ASSOCIATION
SEPTEMBER 16, 17, 1982
HOTEL UTAH — Salt Lake City, Utah

OTHER GUEST SPEAKERS

DONALD F. TEAL, MD
Eugene, Oregon
"Digit Replantation" (Panel member)

ERLE E. PEACOCK, Jr., MD
Tulane University School of Medicine
New Orleans, Louisiana
"Premalignant Breast Disease and Prophylactic Mastectomy" (Panel member)

- ROD HESTER, MD
  Emory University
  Atlanta, Georgia
  "Premalignant Breast Disease and Prophylactic Mastectomy" (Panel member)

- BARTLEY R. FRUEH, MD
  Ann Arbor, Michigan
  "Blepharospasm: Diagnosis and Management"

SPECIALTY SCIENTIFIC SESSIONS

THURSDAY, SEPTEMBER 16, 1982 1:30 to 5:30 pm

Family Practice

Plastic Surgery

- Dermatology
- Ophthalmology
- Obstetrics and Gynecology
- General Surgery
- Pathology, Radiation Oncology

SPECIALTY DINNERS 6:00 PM HOTEL UTAH

ADDED FEATURES:

WEDNESDAY, SEPTEMBER 15
Presidents' Reception and Dinner

FRIDAY, SEPTEMBER 17

Financial Planning Seminar	**9:00 am**
John Snow Memorial Lecture	**12:00 Noon**

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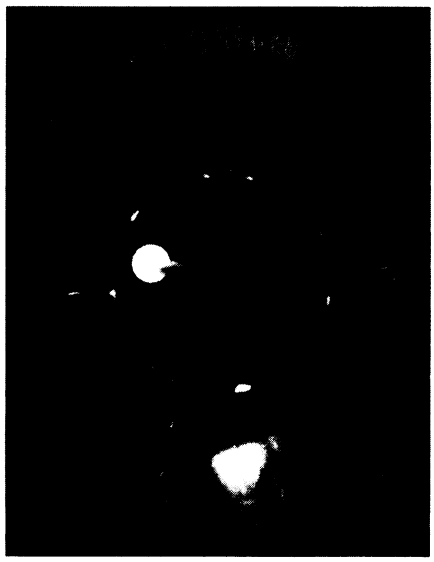
In moderate depression and anxiety

TO SEE THE PATIENT THROUGH THE DAY, ONCE-DAILY DOSAGE... AT NIGHT



Convenience helps compliance

Many patients respond well to a single bedtime dose of Limbitrol, a convenient schedule that may enhance compliance and minimize daytime drowsiness. Others may do best on divided doses, perhaps with the major portion at night. In all cases, caution patients about combined effects with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as driving or operating machinery.

Limbitrol® IV

Tablets 5-12.5 each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)

Tablets 10-25 each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt)

puts anxious depression to rest

LIMBITROL* TABLETS Tranquilizer—Antidepressant
Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety.

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use; then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

***Usage in Pregnancy:* Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.**

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline; symptoms [including convulsions] similar to those with barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in such patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine and similar antihypertensives. Concomitant use with other psychotropic drugs has not been evaluated; sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely. The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs:

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female and elevation and lowering of blood sugar levels.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. I.V. administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single *h.s.* dose may suffice for some patients. Lower dosages are recommended for the elderly.

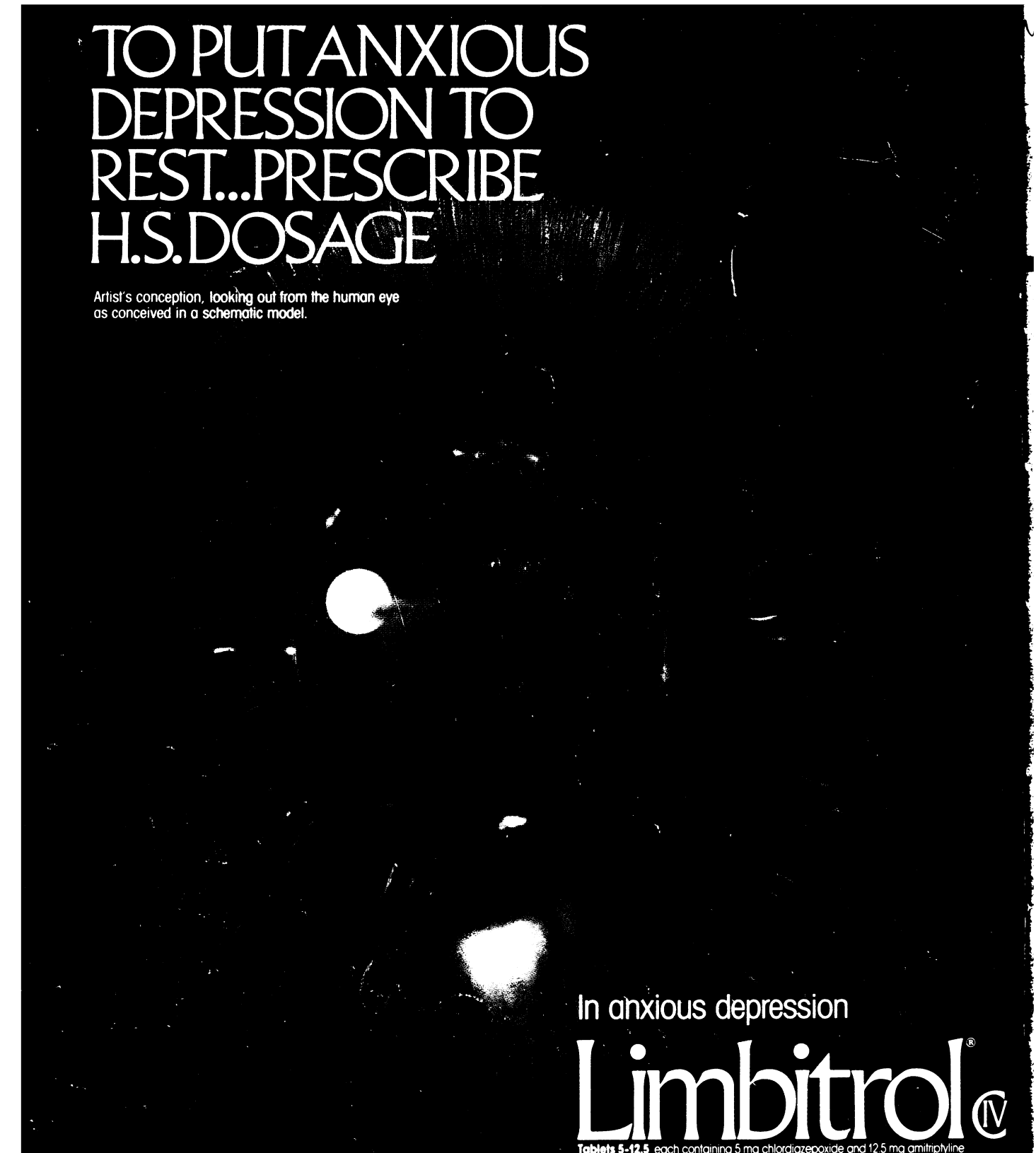
Limbitrol 10-25, initial dosage of three to four tablets daily in divided doses, increased to six tablets or decreased to two tablets daily as required. Limbitrol 5-12.5, initial dosage of three to four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: White, film-coated tablets, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) and blue, film-coated tablets, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500; Tel-E-Dose* packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50.

ROCHE®

Roche Products Inc.
Manati, Puerto Rico 00701

TO PUT ANXIOUS DEPRESSION TO REST...PRESCRIBE H.S. DOSAGE



Artist's conception, looking out from the human eye as conceived in a schematic model.

In anxious depression

Limbitrol® (IV)

Tablets 5-12.5 each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)

Tablets 10-25 each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt)

For broad symptom response, including insomnia

mmary of product information on preceding page.